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External drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults (Review)

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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	4
BACKGROUND	7
OBJECTIVES	7
METHODS	7
RESULTS	9
Figure 1.	10
Figure 2.	12
Figure 3.	13
DISCUSSION	15
AUTHORS' CONCLUSIONS	16
ACKNOWLEDGEMENTS	16
REFERENCES	17
CHARACTERISTICS OF STUDIES	19
DATA AND ANALYSES	30
Analysis 1.1. Comparison 1 Comparison of drains versus no drains, Outcome 1 Recurrence.	31
Analysis 1.2. Comparison 1 Comparison of drains versus no drains, Outcome 2 Complications.	32
Analysis 1.3. Comparison 1 Comparison of drains versus no drains, Outcome 3 Mortality.	32
Analysis 1.4. Comparison 1 Comparison of drains versus no drains, Outcome 4 Poor functional outcome.	32
Analysis 1.5. Comparison 1 Comparison of drains versus no drains, Outcome 5 Sensitivity analysis of recurrence.	33
APPENDICES	33
CONTRIBUTIONS OF AUTHORS	36
DECLARATIONS OF INTEREST	36
SOURCES OF SUPPORT	36
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	36
INDEX TERMS	36

[Intervention Review]

External drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults

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ABSTRACT

Background

Chronic subdural haematoma (CSDH) is one of the most common types of intracranial haematoma, and often occurs in older people. Burr-hole craniostomy, which is an evacuation through one or two burr holes drilled over the site of the haematoma, has been widely accepted as the most effective way to manage CSDH. Recurrences are a major problem and need reoperation, sometimes repeatedly.

Objectives

To assess the effects and safety of the use of external drains versus no drains after burr-hole evacuation for the treatment of CSDH in adults.

Search methods

We ran our first search on 27 November 2014. We searched the Cochrane Injuries Group's Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library), MEDLINE (OvidSP), Embase Classic+Embase (OvidSP), PubMed, ISI WOS (SCI-EXPANDED, SSCI, CPCI-S and CPSI-SSH), Chinese databases, and clinical trials registers, and screened reference lists. In compliance with the MECIR conduct standard 37, the Cochrane Injuries Group Information Specialist ran an update search within 12 months of publication (25 April 2016). We have screened these results but not incorporated the findings into the current review; as a result of the update search, one trial is awaiting classification.

Selection criteria

We included randomized controlled trials (RCTs) that compared external subdural drains with no drains after burr-hole evacuation for the treatment of CSDH in adults.

Data collection and analysis

Two review authors identified potential articles from the literature search, extracted data independently using a data extraction form and assessed risk of bias using the Cochrane 'Risk of bias' tool. For dichotomous data, where statistical heterogeneity was low, we calculated summary risk ratios with 95% confidence intervals using a fixed-effect model.

Main results

Nine RCTs, including a total of 968 participants, reported outcomes specified by this review. Only one RCT reported the use of an adequate method of allocation concealment; this trial was a large, single-centre, high quality study and was adequately reported. All included trials reported a reduced recurrence of CSDH with external subdural drains. We found a significant reduction in the risk of recurrence

with subdural drains (RR 0.45, 95% CI 0.32 to 0.61, $I^2 = 38\%$; 9 studies, 968 participants; moderate-quality evidence). There was no strong evidence of any increase in complications (RR 1.15; 95% CI 0.77 to 1.72, $I^2 = 0\%$; 7 studies, 710 participants; low-quality evidence), mortality (RR 0.78, 95% CI 0.45 to 1.33, $I^2 = 22\%$; 5 studies, 539 participants; low-quality evidence), or poor functional outcome (which included deaths) (RR 0.68, 95% CI 0.44 to 1.05, $I^2 = 31\%$; 5 studies, 490 participants; low-quality evidence).

Authors' conclusions

There is some evidence that postoperative drainage is effective in reducing the symptomatic recurrence of CSDH. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Due to the low quality of the evidence for the secondary outcomes, the effect of drainage on the occurrence of surgical complications, mortality and poor functional outcome is uncertain. This uncertainty can be clarified with data from high-quality studies which may be conducted in the future. There is no strong evidence of any increase in complications when drains are used.

PLAIN LANGUAGE SUMMARY

Use of drains in adults after surgery for chronic subdural haematoma

What is a chronic subdural haematoma (CSDH)?

A chronic subdural haematoma (CSDH) is the slow accumulation of blood between the brain and the membrane that surrounds it. CSDH is a common type of brain (intracranial) haematoma and occurs more frequently in older people. Up to 75% of CSDHs are caused by trauma to the head, though this trauma can be trivial, with no loss of consciousness, vomiting or seizures, or any other post-trauma symptoms. Symptoms of CSDH depend upon the size of the haematoma and the parts of the brain on which it exerts pressure, but may include confusion or coma; memory problems; difficulty speaking, swallowing or walking; drowsiness; headaches; seizures; and weakness or numbness of limbs and face.

How is CSDH treated?

CSDH is treated most effectively through surgery with 'burr-hole evacuation'. In this procedure one or two holes (5 mm to 30 mm wide) are drilled through the skull over the haematoma. The accumulated blood is washed out through these holes. Sometimes, at the end of surgery, surgeons insert a soft silicone drain through one burr hole to continue to drain the space previously occupied by the blood (subdural drainage). These drains remove any fluid that accumulates into an external collection vessel, and stay in place for 24 to 48 hours after surgery before being removed. Alternatively, at the end of surgery, the wounds are closed surgically without insertion of external drains.

Why might drains be important?

Recurrence (i.e. formation of another CSDH in the same place) is a major problem with CSDH, and patients may need additional, repeated surgical procedures to remove them. Drains might reduce recurrence, but are not used routinely. The authors of this Cochrane Review wanted to discover whether the use of external drains after burr-hole surgery for CSDH reduces the risk of recurrence of CSDH.

Study characteristics and key results

The review authors conducted extensive searches of the medical literature up to November 2014 for relevant randomized controlled trials (RCTs), which provide the most reliable evidence. They identified nine RCTs, involving 968 participants, that compared the use of external drains in some patients versus no drains in other patients after burr-hole surgery for CSDH. The trials were conducted in India, Turkey, Iran, Germany, the UK and Japan. All participants were adults, mostly over 60 years of age. All the trials used very similar surgical procedures. Six trials followed participants for six months, the remaining trials followed them for three months, one month, or three weeks (one trial each).

The authors were able to pool the results of the trials statistically, and this showed that use of drains does reduce the risk of recurrence of CSDH after burr-hole surgery by about 50% compared to the risk in the group of patients who did not have drains (the control group). However, there were no clear differences between the drain and no-drain treatment groups for postoperative complications (i.e. infection, seizures or sudden bleeding), death, or functional outcome (i.e. regaining abilities affected by the CSDH).

Quality of the evidence

The results of this review may change in the future when data are available from additional studies. The existing studies have either too few participants or events to give a reliable result, even when the results are pooled. Some of the studies did not describe the randomisation procedures in detail, and are considered to be of lower quality because of this.

Further research will also help to establish:

- the effects of external drains on postoperative complications, death, and functional outcome;
- whether it is better to use one or two burr holes during surgery;

-
- the best way to position the drain's tube within the brain;
 - the best duration of drainage.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Drains compared to no drains for burr-hole evacuation of CSDH in adults

Drains compared to no drains for burr-hole evacuation of CSDH in adults

Patient or population: adults with burr-hole evacuation of CSDH

Settings: hospital settings in India,Turkey, Iran, Germany, UK and Japan

Intervention: one or more drains

Comparison: no drains

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	No drain	Drain				
Overall recurrence Follow-up: 3 weeks-6 months	Study population		RR 0.45 (0.32 to 0.61)	968 (9 studies)	⊕⊕⊕⊖ moderate ¹	
	216 per 1000	97 per 1000 (69 to 132)				
	Moderate					
	231 per 1000	104 per 1000 (74 to 141)				
Recurrence with 2 burr holes (subgroup) Follow-up: 6 months	Study population		RR 0.46 (0.26 to 0.8)	306 (3 studies)	⊕⊕⊖⊖ low ^{1,2}	
	216 per 1000	99 per 1000 (56 to 173)				
	Moderate					
	231 per 1000	106 per 1000 (60 to 185)				
Recurrence with 1 burr hole (subgroup) Follow-up: 6 months	Study population		RR 0.17 (0.05 to 0.56)	156 (2 studies)	⊕⊕⊖⊖ low ^{1,2}	
	211 per 1000	36 per 1000 (11 to 118)				

	Moderate			
	213 per 1000	36 per 1000 (11 to 119)		
Recurrence with 1 or 2 burr holes (subgroup) Follow-up: 3 weeks-6 months	Study population	RR 0.52 (0.34 to 0.79)	506 (4 studies)	⊕⊕⊕⊖ moderate ¹
	218 per 1000	113 per 1000 (74 to 172)		
	Moderate			
	213 per 1000	111 per 1000 (72 to 168)		
Complications Follow-up: 3 weeks-6 months	Study population	RR 1.15 (0.77 to 1.72)	710 (7 studies)	⊕⊕⊖⊖ low ^{1,2}
	110 per 1000	127 per 1000 (85 to 190)		
	Moderate			
	100 per 1000	115 per 1000 (77 to 172)		
Mortality Follow-up: 6 months	Study population	RR 0.78 (0.45 to 1.33)	539 (5 studies)	⊕⊕⊖⊖ low ^{1,2}
	100 per 1000	78 per 1000 (45 to 133)		
	Moderate			
	56 per 1000	44 per 1000 (25 to 74)		
Poor functional outcome (includes death) Follow-up: 6 months	Study population	RR 0.68 (0.44 to 1.05)	490 (5 studies)	⊕⊕⊖⊖ low ^{1,2}
	169 per 1000	115 per 1000 (74 to 177)		
	Moderate			
	131 per 1000	89 per 1000		

(58 to 138)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Only one trial used adequate allocation concealment, and one trial used alternation as a randomisation method ([Wakai 1990](#)).

² Downgraded one level for imprecision: estimate based on few events and wide CIs.

BACKGROUND

Description of the condition

Chronic subdural haematoma (CSDH; a collection of blood between the brain and its outer membrane that forms slowly) is one of the most common clinical entities in daily neurosurgical practice. It is generally a disease of older people, but also occurs during infancy.

The incidence of CSDH increases greatly with age and ranges from approximately 5 per 100,000 per year in the general population (Santarius 2004), to 8 to 58 per 100,000 per year in those over 65 years of age (Cousseau 2001). The proportion of people aged 65 years and older in the population is expected to double worldwide between 2000 and 2030 (Kinsella 2001), so interest in the best treatment for CSDH will increase.

Older people are at particular risk of CSDH because the brain atrophies with age (due to brain cell death). Pathogenesis of CSDH in older people is considered to be linked to gradual, age-related atrophy of the brain that leads to tension on the dural border cell layer and on the points where veins traverse the dura. Even minor trauma may cause one of these veins to tear. Slow bleeding from the low-pressure venous system can enable large haematomas to form before clinical signs appear (Haines 1993).

Most CSDHs are probably caused by head injury. A history of trauma has been obtained in 56% to 75% of patients (Fogelholm 1975a; Richter 1984; Ramachandran 2007), although the trauma is frequently trivial (i.e. involving no loss of consciousness, no vomiting, seizures or any post-traumatic sequelae). Acute subdural haematoma (sudden formation of a subdural haematoma), with or without surgical intervention, can also lead to CSDHs. Other predisposing factors include chronic alcoholism, coagulopathy (problems with coagulation), use of anticoagulants, seizure disorders, and cerebrospinal fluid (CSF) shunts (Fogelholm 1975b; Meagher 2013).

CSDH is not uncommon in infants, but is relatively rare after childhood. In infants, unlike adults, the original blood clot is rarely encapsulated by a fibrous membrane forming a 'subdural hygroma' of similar shape and location to the original haematoma. Infant CSDH more commonly features a widespread fluid accumulation (Squier 2009).

Development of such chronic subdural fluid collections is not well understood. Suggested mechanisms include: osmotic accumulation of fluid and repeated haemorrhage into the healing granulating membrane, or continued exudation, or inflammation of the dural border cell layers (Markwalder 1981). Leakage of CSF through the subarachnoid membrane is considered to play a significant role in chronic subdural fluid collections (Stroobandt 1978).

Description of the intervention

In general, treatment for this disorder is surgical evacuation (removal) and three techniques are most often used: twist-drill craniostomy, which produces a hole with a diameter less than 5 mm; burr-hole craniostomy, which produces a hole with a diameter of 5 mm to 30 mm; and craniotomy in which a portion of the skull is removed to gain access to the haematoma (Mohamed 2003; Muzii 2005; Horn 2006). A meta-analysis showed that all three techniques have about the same mortality rate (2% to 4%) (Weigel

2003). Craniotomy is associated with a much higher morbidity than craniostomy (12.3% versus 3% to 4%); while recurrence of CSDH is much higher with twist-drill craniostomy than with burr-hole craniostomy (33% versus 12.1%), or with craniotomy (33% versus 10.8%) (Santarius 2008). Burr-hole craniostomy, an evacuation via one or two burr holes drilled over the site of the haematoma, with or without drainage, is the most popular surgical technique worldwide. After the holes have been drilled, the subdural collection of blood is washed out with warm saline. Then the holes are sealed surgically, or a drain is inserted for 24 h to 48 h.

How the intervention might work

To prevent recurrences, some neurosurgeons insert a subdural drain, which can be temporary (subdural-to-external) (Gelabert-González 2005), or permanent (subdural-to-peritoneal) (Santarius 2010). Evidence from the last 20 years suggests that use of postoperative drains after burr-hole evacuation of a primary CSDH is associated with a lower recurrence risk (Wakai 1990; Lind 2003; Ramachandran 2007). Surgical techniques, haematoma irrigation and drainage, and insufficient intraoperative and postoperative drainage have been suggested as potential contributors to increased risk of recurrence after surgery.

Why it is important to do this review

Although most CSDHs resolve following a single neurosurgical intervention, approximately 5% to 30% of haematomas recur and require re-rinsing of the subdural fluid space, sometimes repeatedly (Weigel 2003). Drains may reduce recurrence, but are not used routinely. There is little data available in the literature to confirm the impact of using drainage after evacuation and irrigation of the cavity containing the CSDH on the outcome of the patients. It is time to provide clinicians with the best available evidence for the efficacy of external drainage after burr-hole evacuation for the treatment of CSDH, particularly as a large rise in CSDH incidence is expected within the next twenty years (Cousseau 2001).

OBJECTIVES

To assess the effects and safety of the use of external drains versus no drains after burr-hole evacuation for the treatment of CSDH in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials comparing external subdural drains with no drains after burr-hole evacuation for the treatment of CSDH.

Types of participants

People over 18 years of age, in any healthcare setting, who have been clinically diagnosed with CSDH and who have had a burr-hole evacuation.

Types of interventions

Intervention: external subdural drainage after burr-hole evacuation.

Comparison: no drainage.

Types of outcome measures

Primary outcomes

The primary outcome is risk of symptomatic recurrence, defined as reappearance of symptoms and signs attributable to an ipsilateral haematoma identified on a computed tomography (CT) scan within six months of the original drainage procedure.

Secondary outcomes

1. Mortality: all-cause mortality at six months after operation.
2. Postoperative complications: all medical and surgical complications, such as subdural empyema (collection of pus), infection, cardiopulmonary complications.
3. Poor functional outcomes: defined as death or significant dependence in daily activities at six months (4 to 5 on modified Rankin scale (Van Swieten 1988); or 1 to 3 on the Glasgow Outcome Scale Extended (Teasdale 1974); or less than 15 on the Glasgow Coma Scale (Jennett 1975)).

Sample size calculation

Assuming a recurrence risk of 20% for high-risk patients which reduces to 10% with external subdural drainage after burr-hole evacuation, using standard alpha (0.05) and beta (0.10) values, the required sample size is 438 patients in total.

Search methods for identification of studies

In order to reduce publication and retrieval bias we did not restrict our search by language, date, or publication status.

Electronic searches

The Cochrane Injuries Group Information Specialist searched the following sources:

1. Cochrane Injuries Group Specialised Register (27 November 2014);
2. Cochrane Central Register of Controlled Trials (CENTRAL, the Cochrane Library; 2014 Issue 10);
3. Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R) (1946 to 27 November 2014);
4. Embase Classic + Embase (OvidSP) (1947 to 27 November 2014);
5. PubMed (27 November 2014);
6. ISI Web of Science: Science Citation Index Expanded (SCI-EXPANDED) (1970 to November 2014);
7. ISI Web of Science: Conference Proceedings Citation Index-Science (CPCI-S) (1990 to November 2014);
8. Clinicaltrials.gov (clinicaltrials.gov) (accessed 27 November 2014);
9. WHO International Clinical Trials Registry Platform (who.int/ictpr/en/) (accessed 27 November 2014).

In compliance with the MECIR conduct standard 37, the Cochrane Information Specialist ran an update search within 12 months of publication (25 April 2016). We have screened these results, but not incorporated the findings into the current review.

The authors searched the following:

1. The Chinese Biomedical Database (CBM) (1 August 2016);

2. The Chinese National Knowledge Infrastructure (CNKI) (1 August 2016);
3. China Online Journals (1 August 2016).

Search strategies are reported in (Appendix 1 and Appendix 2). We adapted the MEDLINE search strategy as necessary for the other databases. We added the Cochrane Highly Sensitive Search Strategy for identifying randomized trials to the MEDLINE search strategy, and added the search strategy study design terms as used by the UK Cochrane Centre to the Embase strategy (Lefebvre 2011).

Changes to search methods are noted in [Differences between protocol and review](#).

Searching other resources

We screened the reference lists of relevant published papers and all included studies.

Data collection and analysis

Selection of studies

The Cochrane Injuries Group Information Specialist collated the results of the electronic database searches and removed duplicates.

Two review authors (Zhu Y and Peng D) independently performed a preliminary screening of titles and abstracts considering the type of trial, participants, and intervention. In the event of disagreement, we would have discussed any differences of opinion. If disagreement persisted, we would have selected trials for inclusion on the basis of the full-text article. We assessed the full-text articles of the selected trials to examine eligibility and had no disagreements about inclusion. As stated in our protocol, if we had had any disagreements, we would have consulted our colleague, Ruxin Xing, who is an experienced author.

Data extraction and management

Using a predesigned form for this review, the two review authors (Zhu Y and Peng D) extracted information independently on aspects of trial design and risk of bias (including method of randomisation and allocation concealment, blinding of participants, blinding of outcome assessment, incomplete follow-up, selective reporting, and other sources of bias), study characteristics (types of participants, interventions, and outcomes), as well as outcome data, and compared their results.

Assessment of risk of bias in included studies

We evaluated each included trial for risk of bias in six domains (i.e. sequence generation, allocation concealment, blinding, incomplete outcome data, potential for selective reporting and other sources of bias); we rated each domain as being at low, high or unclear risk of bias. Two review authors (Zhu Y and Peng D) made assessments for each domain independently using the 'Risk of bias' assessment tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Measures of treatment effect

For dichotomous data, we calculated the risk ratio (RR) and 95% CI. We calculated the mean difference (MD) and 95% CI for continuous outcomes that were measured on the same scale; for continuous

outcomes measured on different scales we planned to calculate the standardised mean difference.

Unit of analysis issues

We included trials where the unit of allocation was the individual participant; we did not exclude any trials on this basis, as all trials randomized individual participants.

Dealing with missing data

For included studies, we noted levels of attrition. We defined 'high levels' of missing data as more than 20% of participants lost to follow-up. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis, which showed our result was robust. For all outcomes, we carried out analyses based on available data.

Assessment of heterogeneity

We explored both clinical and statistical heterogeneity. We examined trial characteristics in terms of participants, interventions, and outcomes for evidence of clinical heterogeneity. We planned to assess statistical heterogeneity using the χ^2 test, which examines the presence of heterogeneity, and the I^2 statistic, which assesses the extent of inconsistency between trials (Higgins 2003). We considered trials to be statistically heterogeneous if the I^2 statistic value was over 50% and the P value was less than 0.10 in the χ^2 test (Deeks 2011). We explored possible sources of heterogeneity through sensitivity analysis.

Assessment of reporting biases

When a sufficient number of trials (10 or more) becomes available, we plan to assess publication bias by using funnel plots (Sterne 2011).

Data synthesis

We performed statistical analysis using Review Manager 2014 (RevMan) and conducted meta-analysis where the included trials were clinically homogeneous and there was no evidence of substantial statistical heterogeneity (I^2 statistic value less than 75%, P value greater than 0.10) (Deeks 2011). For dichotomous outcomes, we planned to use the Mantel-Haenszel method and to report the results as RR with 95% CI. We planned to provide a narrative summary of study results if it was not possible to pool the data (I^2 statistic value was over 75% and the P value was less than 0.10 in the χ^2 test).

Subgroup analysis and investigation of heterogeneity

If significant heterogeneity had been present, and the number of included studies had been sufficient, we planned to explore the effects of different study characteristics to determine possible causes of heterogeneity.

Had there been enough studies, we planned to perform subgroup analyses of:

1. different age groups;
2. severity of brain injury (severe = GCS 8 or less, moderate = GCS 9 to 12, mild = GCS 13 or over) (Teasdale 1974);
3. number of burr holes (one or two);
4. type of drain (inserted frontal-ward or occipital-ward, passive or active drainage);
5. anticoagulation treatment.

Sensitivity analysis

We planned to test the robustness of the evidence by performing sensitivity analyses of pooled data in which we repeated the analysis excluding studies:

1. at high or unknown risk of selection bias (due to inadequate methods of allocation concealment);
2. with missing data; and
3. comparing the results of the fixed-effect model to the random-effects model (robust evidence should not be reversed by changing the model).

Summarising and interpreting results

We used the GRADE approach to assess the quality of evidence for each of the key outcomes. We used the GRADE profiler to import data from RevMan and create 'Summary of findings' tables (GRADEpro GDT 2014; Review Manager 2014).

In our assessments of the overall quality of evidence for each outcome that included pooled data, we downgraded the evidence from 'high quality' by one level for serious (or by two for very serious) study limitations (risk of bias), indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

RESULTS

Description of studies

Results of the search

The search was performed by the Cochrane Injuries Group's Information Specialist (27 November 2014). The search identified 4610 records from the databases outlined in Electronic searches. There were 4562 records after duplicates were removed. We screened all titles and abstracts for inclusion in the review. We excluded 4406 obviously ineligible studies at this point, and assessed 156 full-text articles for eligibility. Following this, we excluded 138 texts. One record was identified through the reference lists of included trials (Ahmed 2011). We included nine trials in the qualitative and quantitative syntheses (see Figure 1 and Characteristics of included studies). We did not identify any potentially eligible trials from other sources.

Figure 1. Study flow diagram

In total, we included nine trials ([Laumer 1989](#); [Wakai 1990](#); [Tsutsumi 1997](#); [Erol 2005](#); [Santarius 2009](#); [Ahmed 2011](#); [Javadi 2011](#); [Kutty 2014](#); [Singh 2014](#)) and excluded eight ([Hennig 1999](#); [Williams 2001](#); [Okada 2002](#); [Lind 2003](#); [Gurelik 2007](#); [Kiyamaz 2007](#); [Sindou 2010](#); [Sarnvivad 2011](#)). We identified one ongoing trial ([NCT01785797](#)).

From the updated search (25 April 2016) we screened 496 new references and found one new study, which we have placed in [Studies awaiting classification](#). This study will be incorporated into the next version of the review, if appropriate, once we have obtained details of the randomisation process.

Included studies

See the [Characteristics of included studies](#) for details of the nine included studies.

Design

Six trials described the method of randomisation. [Erol 2005](#), [Laumer 1989](#) and [Javadi 2011](#) did not describe any details of randomisation. All trials had two groups (one drain group and one control group) except [Laumer 1989](#), which had three groups, one of which concerned internal drains, and so was not included in our analysis. Only [Santarius 2009](#) reported the method of allocation concealment. All nine trials were conducted in single centres.

Sample sizes

[Ahmed 2011](#) recruited 51 participants. [Erol 2005](#) recruited 70 participants. [Javadi 2011](#) recruited 40 participants. [Kutty 2014](#) recruited 140 participants. [Laumer 1989](#) recruited 144 participants. [Santarius 2009](#) recruited 215 participants. [Singh 2014](#) recruited 200 participants. [Tsutsumi 1997](#) recruited 118 participants. [Wakai 1990](#) recruited 38 participants.

Setting

[Ahmed 2011](#), [Singh 2014](#) and [Kutty 2014](#) were conducted in India. [Erol 2005](#) was conducted in Turkey. [Javadi 2011](#) was conducted in Iran. [Laumer 1989](#) was conducted in Germany. [Santarius 2009](#) was conducted in UK. [Tsutsumi 1997](#) and [Wakai 1990](#) were conducted in Japan.

Participants

All trials recruited adults with symptomatic CSDH proven by computed tomography (CT) or magnetic resonance imaging (MRI) scan. Five trials excluded people with ipsilateral haematomas who had undergone CSF diversion, or in whom surgery other than burr-hole evacuation was indicated, or who did not need surgical treatment because of the size of CSDH or their clinical status, or had been operated on once or more for previous CSDH, or had calcified or ossified CSDHs ([Tsutsumi 1997](#); [Santarius 2009](#); [Ahmed 2011](#); [Javadi 2011](#); [Singh 2014](#)). [Kutty 2014](#) and [Wakai 1990](#) excluded people with bleeding diathesis or using oral anticoagulants. Two trials did not report the details of exclusion criteria ([Laumer 1989](#); [Erol 2005](#)). There were more men than women in all the trials. The age and sex distribution of the participants was clear in all studies except for [Laumer 1989](#) and [Singh 2014](#).

Interventions

All interventions were very similar, with the biggest difference from a surgical viewpoint being the number of burr holes used. Single

([Wakai 1990](#); [Tsutsumi 1997](#)), or double ([Santarius 2009](#); [Ahmed 2011](#); [Javadi 2011](#)), burr holes were drilled over the maximum width of the haematoma. In three trials the number of burr holes to be made was left to the discretion of the operating surgeon ([Laumer 1989](#); [Erol 2005](#); [Singh 2014](#)), but in [Kutty 2014](#) the surgeon drilled one hole for participants in the drains group, and two holes for participants in the no-drains group. Surgery was done under local or general anaesthesia. The dura mater was opened with a cruciate incision, and coagulated with bipolar diathermy. The subdural collection of blood was washed out with warm Ringer's lactate saline or normal saline. When a participant was assigned to the no-drain group, the subdural space was filled with Ringer's lactate saline or normal saline and the scalp closed in two layers. Those assigned to the drain group had a soft silicone drain inserted into the subdural space through the burr hole, and tunnelled for a minimum of 5 cm away from the scalp incision. The subdural space was filled with Ringer's lactate saline or normal saline and the scalp was closed in two layers. The drain was connected to a soft collection bag that was kept for 24 h to 48 h and then removed. Bilateral CSDHs were treated as one case, and both sides received the same treatment.

Outcomes

In all nine trials the primary outcome measure was the risk of recurrence, defined as the risk of reoperation to treat recurrent chronic subdural haematoma in a participant. However, two studies performed CT scanning in all participants, with and without symptoms, within a month of surgery, and defined recurrent CSDH as either worsening neurological symptoms or haematoma increase on CT ([Laumer 1989](#); [Erol 2005](#)). The other seven trials used the presence of both worsening neurological symptoms and haematoma increase on CT as an indication for reoperation.

The secondary outcomes included surgical complications (subdural empyema, acute haematoma, meningitis, seizure, fever, cardiopulmonary complications, etc.); mortality and clinical outcomes measured by the Glasgow Outcome Score (GOS), and Modified Rankin Score (MRS); and neurological deficits (i.e. limb weakness or dysphasia). [Tsutsumi 1997](#) and [Kutty 2014](#) did not report complications, but we analyzed complication risk in the other seven studies. Three studies did not report mortality and clinical outcome ([Laumer 1989](#); [Tsutsumi 1997](#); [Kutty 2014](#)).

Follow-up in the [Laumer 1989](#) study was only three weeks in duration. [Erol 2005](#) used a follow-up of one month, [Kutty 2014](#) used a follow-up of three months; follow-up in the other six trials was six months.

Excluded studies

We excluded eight studies for reasons detailed in [Characteristics of excluded studies](#). None of the excluded trials were RCTs, and some were done retrospectively ([Okada 2002](#); [Lind 2003](#); [Kiyamaz 2007](#); [Sarnvivad 2011](#)).

Risk of bias in included studies

See [Figure 2](#) and [Figure 3](#) for summaries of the results of the 'Risk of bias' assessment.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies. Nine studies are included in this review.

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ahmed 2011	+	?	+	+	+	+	+
Erol 2005	?	?	+	+	+	+	+
Javadi 2011	?	?	+	+	+	+	+
Kutty 2014	+	?	+	+	+	+	+
Laumer 1989	?	?	+	+	+	+	+
Santarius 2009	+	+	+	+	+	+	+
Singh 2014	+	?	+	+	+	+	+
Tsutsumi 1997	+	?	+	+	+	+	+
Wakai 1990	-	?	+	+	+	+	+

Allocation

We judged that five of the nine included trials used adequate methods of randomisation with regard to sequence generation (Tsutsumi 1997; Santarius 2009; Ahmed 2011; Kutty 2014; Singh 2014). Another three trials were described as randomized (Erol 2005; Javadi 2011; Laumer 1989), but the methods of random sequence generation used were not clear from their trial reports. One trial used an alternate method of randomisation by assigning participants sequentially to drains or no-drains (Wakai 1990), this method of allocation has a high risk of bias. Only one trial described the use of sealed envelopes labelled with sequential study numbers (Santarius 2009), and so was rated as being at low risk of bias for this domain; we rated the other eight trials as being at unclear risk of bias.

Blinding

The nature of this intervention did not allow for masking of treatment allocation, so performance bias was inevitable in these nine trials. Outcome assessment for recurrence (which was defined as both worsening of neurological symptoms and haematoma increase on CT scan), mortality and complications of operation was objective, so, with the exception of Santarius 2009 and Javadi 2011, no studies used blinding. We judged that the performance bias and detection bias had little effect on the outcome assessment, and thus each trial was at low risk of bias for this domain.

Incomplete outcome data

All the included trials reported our primary outcome with no missing data, and only the Santarius 2009 trial had data missing for secondary outcomes. In the trial report the authors said that 50 participants did not respond to the postal questionnaire and one no longer wished to take part. Since the missing data were due to failure to respond to the postal questionnaire, we did not write to the trialists, as they would not have had the data. We performed analyses on both an intention-to-treat (ITT) basis and per protocol basis (PP) for missing data for poor functional outcome. When we performed a sensitivity analysis by removing the Santarius 2009 trial, the result was still robust (Analysis 1.5).

Selective reporting

We were able to check only one registered protocol (Santarius 2009), and found no reporting bias. Although we could not check the protocols, a further six trials reported important data (such as recurrence, complications, outcome, and mortality), therefore we judged the potential for reporting bias to be low for these seven trials. Two trials, Tsutsumi 1997 and Kutty 2014, reported our primary outcome only, but we found no selective reporting (although important outcomes, such as complications and mortality, were not reported).

Other potential sources of bias

We judged all nine trials to be at low risk of bias for this domain.

Effects of interventions

See: [Summary of findings for the main comparison Drains compared to no drains for burr-hole evacuation of CSDH in adults](#)

Risk of recurrence

The nine trials included a total of 968 participants. There were 47 cases of recurrent CSDH among 492 participants (9.6%) with a drainage system in place compared with 103 cases of recurrent CSDH in the 476 participants without a drainage system in place (21.6%). A fixed-effect meta-analysis showed a pooled RR of 0.45 (95% CI 0.32 to 0.61; $P < 0.00001$; $I^2 = 38\%$; Analysis 1.1). There was no indication of substantial statistical heterogeneity between the results of the different trials ($\text{Chi}^2 = 12.89$; $P = 0.12$).

Sensitivity analysis

We performed a sensitivity analysis by removing the two short-term studies (Laumer 1989; Erol 2005), and found a pooled RR of 0.33 (95% CI 0.22 to 0.50; $P < 0.00001$; $I^2 = 0\%$; Analysis 1.5). There was no indication of statistical heterogeneity between the results of the different trials ($\text{Chi}^2 = 4.28$; $P = 0.64$). Since only one trial used adequate allocation concealment (Santarius 2009), we did not perform a sensitivity analysis in which we excluded studies with a high risk of bias for allocation concealment. We rated the quality of the evidence for this outcome as moderate because of risk of bias.

Subgroup analyses

We performed additional subgroup analysis according to the numbers of holes used during surgery. Three trials used double holes over the maximum width of the haematoma (Santarius 2009; Ahmed 2011; Javadi 2011), while two used single holes (Wakai 1990; Tsutsumi 1997), and the remaining four trials used a mixture of one or two holes. The three subgroups all showed a lower risk of recurrence in the drains treatment group. A fixed-effect meta-analysis of double holes showed a pooled RR of 0.46 (95% CI 0.26 to 0.80; $P = 0.006$; $I^2 = 0\%$). There was no indication of statistical heterogeneity between the results of the different trials ($\text{Chi}^2 = 1.11$; $P = 0.57$; Analysis 1.1). We rated the quality of the evidence for this outcome as low for risk of bias and imprecision (estimate based on few events and wide CIs). A fixed-effect meta-analysis of single holes showed a pooled RR of 0.17 (95% CI 0.05 to 0.56; $P = 0.004$; $I^2 = 0\%$). There was no indication of statistical heterogeneity between the results of the different trials ($\text{Chi}^2 = 0.02$; $P = 0.88$; Analysis 1.1). We rated the quality of the evidence for this outcome as low for risk of bias and imprecision (estimate based on few events and wide CIs). A fixed-effect meta-analysis of single or double holes showed a pooled RR of 0.52 (95% CI 0.34 to 0.79; $P = 0.002$; $I^2 = 63\%$; Analysis 1.1). We rated the quality of the evidence for this outcome as moderate for risk of bias. The sensitivity analysis showed that the two short-term studies, Laumer 1989 and Erol 2005 were the source of the heterogeneity (Analysis 1.5).

We did not perform other subgroup analyses because the trials did not offer sufficiently detailed data.

Secondary outcomes

Complications

Two trials did not report complications (Tsutsumi 1997; Kutty 2014). We analyzed the remaining seven studies for risk of complications. These seven trials included 710 participants. There were 45 complications amongst 357 participants with drains (12.6%) compared with 39 complications among 353 participants without drains (10.8%). A fixed-effect meta-analysis showed a pooled RR of 1.15 (95% CI 0.77 to 1.72; $P = 0.50$; $I^2 = 0\%$; Analysis 1.2).

No indication of statistical heterogeneity between the results of the different trials was present ($\text{Chi}^2 = 5.63$; $P = 0.47$). We downgraded the quality of the evidence for this outcome from high to low quality because of risk of bias and imprecision (estimate based on few events and wide CIs).

Mortality

Five studies with a total of 539 participants could be analyzed for mortality at six months. There were 21 deaths among 270 participants with drains (7.8%), compared with 27 deaths among 269 participants without drains (10%). A fixed-effect meta-analysis showed a pooled RR of 0.78 (95% CI 0.45 to 1.33; $P = 0.35$; $I^2 = 22\%$; Analysis 1.3). No indication of statistical heterogeneity between the results of the different trials was present ($\text{Chi}^2 = 5.11$; $P = 0.28$). There were few missing values for the outcome measures (less than 2.5%), so incomplete data for a response variable will not bias the results. We downgraded the quality of the evidence for this outcome from high to low quality because of risk of bias and imprecision (estimate based on few events and wide CIs).

Poor functional outcome

We defined poor functional outcomes as death or significant dependence in daily activities at six months (see [Types of outcome measures](#) for details). The figures presented here are for the combined outcome of death plus disability/dependence.

Five studies could be analyzed for poor functional outcome at six months. There were 27 poor outcomes among 241 participants with drains (11.2%), compared with 42 poor outcomes among 249 participants without drains (16.9%). A fixed-effect meta-analysis showed a pooled RR of 0.68 (95% CI 0.44 to 1.05; $P = 0.08$; $I^2 = 31\%$; Analysis 1.4). No indication of statistical heterogeneity between the results of the different trials was present ($\text{Chi}^2 = 5.77$; $P = 0.22$). We downgraded the outcome from high quality to low quality for risk of bias and imprecision (estimate based on few events and wide CIs).

DISCUSSION

This systematic review summarises the evidence from randomized controlled trials (RCTs) of external drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults.

Summary of main results

Nine RCTs with a total of 968 participants met the inclusion criteria for this review. These trials were homogeneous in their objectives, participant characteristics, operative method, and outcome measures. Only one trial reported the use of adequate allocation concealment methods ([Santarius 2009](#)); this was a large, single-centre, high-quality and adequately reported RCT. The effect of external subdural drains on the recurrence risk for chronic subdural haematomas (CSDH) was reported in all the included trials. We found a statistically significant reduction in the risk ratio (RR) for recurrence when a subdural drain was fitted (RR 0.45, 95% CI 0.32 to 0.61). Heterogeneity between the results of the different trials was acceptable ($\text{Chi}^2 = 12.89$; $P = 0.12$; $I^2 = 38\%$). The result was robust even when we used the random-effects model. We did not perform a sensitivity analysis based on the quality of allocation concealment status, because only one trial used adequate allocation concealment.

The sensitivity analysis we performed by removing the two short-term studies found that I^2 was 0% and the RR was also smaller ([Laumer 1989](#); [Erol 2005](#)). With a shorter follow-up time we would have expected the recurrence risk to be lower, as fewer people would present with symptoms of recurrence within the shorter time frame. However, our analysis showed that these two studies with shorter follow-up times had higher risks of recurrence. We reviewed the studies and noted that clinical heterogeneity may contribute to this result, as there were differences in the definition of recurrence and in follow-up times between trials. In the other trials, imaging was done if participants developed a recurrence of their original symptoms, or new symptoms suggestive of raised intracranial pressure, and routine postoperative imaging was not employed. These seven studies defined recurrence as the reappearance of clinical symptoms after initial surgery with computed tomography (CT) scans providing evidence of CSDH on the same site. However, the two short-term studies, [Laumer 1989](#) and [Erol 2005](#), performed CT scanning on all participants within the first month after surgery, whether they had symptoms of recurrence, or not. The high level of recurrence in the participants in these two studies is a result of the detection of radiological recurrence of CSDH in the absence of clinical symptoms or in participants suffering from minimal complaints only. With a modified follow-up regimen, these cases that were detected early might be resolved without reoperation.

Data on complications were not available for two trials ([Tsutsumi 1997](#); [Kutty 2014](#)). Mortality and poor functional outcome were not reported in three trials ([Laumer 1989](#); [Tsutsumi 1997](#); [Kutty 2014](#)). The pooled risk ratio for surgical complications within six months was 1.15 (95% CI 0.77 to 1.72; $P = 0.50$), and the pooled risk ratio for mortality at six months was 0.78 (95% CI 0.45 to 1.33; $P = 0.35$). The results show that there is no clear difference in mortality and surgical complications between participants with a drain and those without a drain. The pooled risk ratio for poor functional outcome (i.e. death and disability) was 0.68 (95% CI 0.44 to 1.05; $P = 0.08$). These results were robust even when we changed the fixed-effect model to the random-effects model or used intention-to-treat analysis.

The prespecified subgroup analysis of the number of burr holes used by the surgeons shows that insertion of a postoperative drain reduced the recurrence risk for CSDH regardless of whether a single hole or double holes were used. It seems to be that drainage via a single burr hole results in a lower recurrence risk (RR 0.17) than drainage with double holes (RR 0.46) compared with no drainage.

Overall completeness and applicability of evidence

This review suggests that the existing evidence on effectiveness of external subdural drainage after burr-hole evacuation of CSDH is reasonable. We identified nine relevant RCTs with a total of 968 participants. Although individual studies actually had small numbers of participants, the trials were homogeneous with respect to the characteristics of participants (for age and sex distribution), treatment methods (burr hole at the maximum width of the haematoma, insertion of a subdural tube after irrigation), duration of treatment (drain in place for one to two days after surgery), and outcome measures (seven out of nine trials used the same definition for the primary outcome of recurrence of CSDH). A different definition was used in two studies, which also had short follow-up times, and this introduced clinical heterogeneity, although, overall, the level of statistical heterogeneity was acceptable. The outcomes, especially the primary outcome, could

be combined in meta-analysis and a robust conclusion could be drawn.

The insertion of an external subdural drain after burr-hole evacuation treatment for CSDH reduces the risk of recurrence. We did not identify any evidence that showed that external subdural drains increased the risk of surgical complications, poor function outcome or mortality. As the insertion of an external subdural tube is inexpensive and easy to perform, and the participants studied in the these trials were located in different healthcare settings worldwide, this procedure could readily be added to the normal medical and surgical management of chronic subdural haematoma patients in hospitals around the world.

Quality of the evidence

We judged only one of the trials to be at a low risk for the method of allocation concealment and so the risk of bias in the remaining trials was high. We assessed the quality of the evidence using GRADE, and judged the evidence for recurrence risk as being of moderate quality, as it was downgraded one level due to a high risk of bias for allocation concealment. We judged the evidence to be of low quality for complications, mortality and poor functional outcome; these were downgraded two levels due to a high risk of bias for allocation concealment and wide confidence intervals.

The complete GRADE evidence profile is presented in [Summary of findings for the main comparison](#).

Potential biases in the review process

The process of searching for studies was thorough. We followed the review protocol strictly in the process of study selection, data extraction, and analysis. Despite the robustness of the pooled analysis, there were some limitations in the review process that may have resulted in potential biases. Firstly, we did not try to obtain missing information from trial investigators. Missing data exceeded 20% for a secondary outcome in [Santarius 2009](#). One of the included trials used alternation as the means of randomisation, which is a method at high risk of bias. Three of the studies did not report on random sequence generation and only one trial reported a low-risk method for allocation concealment.

Agreements and disagreements with other studies or reviews

Two other systematic reviews and meta-analyses, [Liu 2014](#) and [Gabriel 2014](#), included six and seven RCTs respectively. They did not include two of the trials we included ([Kutty 2014](#); [Singh 2014](#)), because they had not been published. As with our findings, these reviews saw little clinical and statistical heterogeneity in the included studies. According to [Gabriel 2014](#), [Liu 2014](#) and our pooled analyses of included RCTs, the risk of overall symptomatic

recurrence was significantly reduced with the use of external subdural drains, and there were no clear differences between the two intervention groups for medical or surgical complications, or poor functional outcome and mortality. While the [Gabriel 2014](#) pooled analysis showed that subdural drains were associated with a better functional recovery - which our analysis did not demonstrate - one of the trials included in [Gabriel 2014](#) did not include deaths within the poor functional outcome category ([Wakai 1990](#)), and this may account for the difference in results.

AUTHORS' CONCLUSIONS

Implications for practice

There is moderate-quality evidence that use of external postoperative drainage is effective for reducing the risk of recurrence of symptomatic chronic subdural haematoma (CSDH). Due to the low quality of the evidence for secondary outcomes, the effect of drains on the occurrence of surgical complications, mortality and poor functional outcome in the postoperative period are uncertain.

Implications for research

One large, single-centre, high-quality and adequately reported, randomized controlled trial (RCT) has already been included in our review. However, there still is a need for large, multicentre, high-quality RCTs that assess the relative effects of external subdural drains on functional recovery, and other different aspects of the burr-hole evacuation of CSDH, such as single versus double burr holes, position of the draining catheter, irrigation or no irrigation, and duration of drainage. These trials must address the methodological weaknesses and protocol inconsistencies identified within this review including: methodological aspects (trials should be well controlled, with adequate methods employed for generating randomisation sequences and concealing allocation); adequate length of follow-up; and contain data on important outcomes (complications, mortality etc.).

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Peng 2014

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ahmed 2011

Methods	Randomised controlled trial, single-centre (India)
Participants	<p>51 participants (45 men and 6 women with an age range of 17-85 years, mean 53 ± 15 years) with diagnosis of CSDH based on CT/MRI study of brain</p> <p>Exclusion criteria: children below 17 years of age; people who had already had surgery for CSDH (i.e. recurrence); people who had had a CSF diversion procedure who subsequently developed CSDH; and people with CSDH for whom burr-hole evacuation was not the surgical approach used</p>
Interventions	<p>All participants had 2 burr holes inserted over the maximum width of the haematoma</p> <p>Group 1: no drains</p> <p>Group 2: drains; continuous closed drainage for 48 h. A soft silicone drain (external diameter 2 mm and length of 20 cm) was inserted into the subdural space through the burr hole overlying the large part of the subdural cavity and tunnelled for a minimum of 5 cm away from the scalp incision</p>
Outcomes	Primary outcome: recurrence risk, defined as reappearance of clinical symptoms after a minimum period of 1 month after initial surgery with evidence of CSDH on the same site on plain CT head scan

Ahmed 2011 (Continued)

Secondary outcomes: GOS score, mortality at discharge and at 6 months, and complications of operation

Notes

Duration of follow-up 6 months. The primary outcome and complications of the operation were measured for all participants

The study was conducted between September 2008 and March 2010

Quote: "The protocol was approved by the institutional ethics committee" p. 18

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization done using random allocation software (version 1.0)" p. 18 Review authors' comment: no reference to the software was provided
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome and complications of operation were measured for all participants. Mortality and clinical recovery measured by GOS score at discharge were recorded in all
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Erol 2005

Methods	Randomised controlled trial, single-centre (Turkey)
Participants	70 participants (54 men and 16 women) requiring surgery for CSDH Exclusion criteria: details not provided
Interventions	Participants were treated with 1 or 2 burr holes at the surgeon's discretion Group 1: no drains; frontal or parietal burr holes on the side of the haematoma without drains Group 2: drains; burr hole with a 2.7 mm subdural drain in place for 48 h and then removed
Outcomes	Primary outcome: recurrence risk

Erol 2005 (Continued)

Secondary outcome measures: clinical recovery, mortality, postoperative complications and length of hospital stay

Notes
Duration of follow-up: 1 month
The study took place between 1994 and 2002

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details in text. Quote: "...were randomly assigned" p. 261
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary and secondary outcome was measured for all participants
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Javadi 2011

Methods	Randomised controlled trial, single-centre, parallel trial (Tehran, Iran)
Participants	40 participants (28 men and 12 women with an age range of 18-96 years, mean = 67 years) were randomized with the balanced block method into 2 groups Exclusion criteria: people under 18 years of age; with images showing calcified or organised haematoma; severe comorbidity, end-stage diseases or secondary haematoma after a shunting procedure, tumour infiltration, or a history of previous craniotomy
Interventions	All participants had 2 burr holes inserted Group 1: no drains Group 2: drains; a blunt-tip, side-hole, 3-mm internal diameter catheter was placed in the cavity after burr-hole evacuation. The drain was connected to a sterile closed-system bag adjusted at the level of patient's head without any negative pressure for 48 h and then removed
Outcomes	Primary outcome measure was recurrence risk, which was defined as the risk of reoperation to treat recurrent chronic subdural haematoma. The recurrence of CSDH was defined as progressive neurological deficits or having no improvement apparently correlated with mass effect in the control CT scan

Javadi 2011 (Continued)

Secondary outcome measures included GOS score, mortality and complications of acute subdural haematoma, cardiopulmonary complications, seizure, meningitis, and any significant surgical complications

Notes

Every participant received follow-up care for at least 6 months

The study was conducted between June 2007 and July 2009

Ethics approval for the study was obtained from the Institutional Review Board p. 732

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study was randomized with the balanced block method but we do not know how Quote: "...were randomized with the balanced block method into two groups..." p. 733
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were each examined by an independent observer. In the cases in which the independent observer confirmed the recurrence of CSDH, the outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary and secondary outcome was measured for all participants
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Kutty 2014

Methods	Randomised control trial, single-centre (India)
Participants	140 participants (113 men and 27 women between 32-98 years of age, mean age = 64.86 years) with radiologically proven CSDH requiring burr-hole evacuation Exclusion criteria: people under 18 years of age; those using oral anticoagulants; and those with bleeding diathesis
Interventions	Group 1: no drains; 2 burr holes (frontal and parietal) on the site of the haematoma Group 2: drains; a single parietal burr hole with a subdural drain (sterile No. 8 infant feeding tubes) present for 48 h-72 h and then removed
Outcomes	Primary outcome: recurrence risk

Kutty 2014 (Continued)

Notes Duration of follow-up: 3 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The patients who qualified for the study were divided into two groups using a randomization chart. No matching was done for age or sex." p. 495
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome was measured for all participants
Selective reporting (reporting bias)	Low risk	Important data (such as complications, outcome, and mortality) were not presented, but there was no evidence of selective reporting
Other bias	Low risk	No other bias detected

Laumer 1989

Methods	Randomised controlled trial, single-centre (Germany)
Participants	144 adults with CSDG Exclusion criteria: details not provided
Interventions	Participants in Group 1 all received a slightly enlarged frontoparietal burr hole. The trial report did not provide details about the number or location of holes for participants in Group 2 and Group 3 Group 1: internal drains; permanent subdural drain with subcutaneous reservoir after burr-hole evacuation (not included in our analysis, as drain was internal, not external) Group 2: external drains; burr-hole evacuation with external closed system drainage Group 3: no drains; burr-hole evacuation without drainage
Outcomes	Primary outcome: reoperation risk; reoperation defined as required when: 1) an initial neurological deficit was increasing, recurring, or not improving and the CT showed a corresponding space-occupying lesion; 2) if there was an increase in the size of haematoma with or without neurological deterioration; 3) if there was permanent or recurrent severe headache with corresponding findings on CT scan Secondary outcome: complication risks of operation such as infection, seizures
Notes	The follow up duration was only 3 weeks

Laumer 1989 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the sequence of the 3 possible operative procedures for all patients included in the study was randomly assigned" Quote: "were randomly divided into three treatment groups" (Abstract)
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome was measured for all participants
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Santarius 2009

Methods	Randomised controlled trial, single-centre (Cambridge, UK)
Participants	215 participants (160 men and 55 women, age range 36-95 years, mean age 76.8 years) who presented with symptomatic CSDH proven by CT scan requiring burr-hole drainage Exclusion criteria: people treated for ipsilateral haematomas within 6 months of presentation; those with a CSF shunt in situ; those in whom surgery other than burr-hole evacuation was indicated; and those for whom the operating surgeon judged drain insertion to be unsafe
Interventions	All participants had 2 burr holes inserted Group 1: no drains Group 2: drains; a soft silicone drain inserted into the subdural space after burr-hole evacuation. The drain was connected to a soft collection bag that was kept in a dependent position for 48 h and then removed
Outcomes	Primary outcome measure was recurrence risk. Recurrence was defined as the occurrence of symptoms and signs attributable to an ipsilateral haematoma seen on a CT scan within 6 months of the original drainage procedure Secondary outcome measures were clinical outcome (mortality, MRS scores, GCS) at discharge and at 6 months, and length of hospital stay for neurosurgery

Santarius 2009 (Continued)

Notes

The primary outcome and duration of neurosurgical hospital admission was measured for all participants. Mortality at 30 days and 6 months was recorded in all but 3 participants with drains and 2 without drains

Study registration number: ISRCTN 97314294

The study was conducted between November 2004 and November 2007

Approved by the Cambridge Local Ethics Research Committee in October 2004, reference number: 04/Q0108/52

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Block randomisation was used, with random sizes of blocks ranging from eight to 12 in an allocation ration of 1:1. Randomisation was done by the investigators with a web-based randomisation software—Random Allocation Software version 1.0." p. 1069
Allocation concealment (selection bias)	Low risk	Quote: "Instructions to use or not use drain were kept in sealed envelopes labelled with sequential study numbers, which were opened at surgery after drain insertion was judged to be safe." p. 1069
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The nature of this intervention did not allow for masking of treatment allocation." p. 1069
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Data were anonymised and clinicians were masked to outcomes when possible." p. 1069
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome was measured for all participants. Analyses were done on an intention-to-treat basis for missing data for secondary outcome measures
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Singh 2014

Methods	Randomised controlled trial, single-centre (India)
Participants	<p>200 adults with symptomatic CSDH proven by CT scan, and randomized into 2 groups once subdural haematoma was evacuated and drain placement was not contraindicated pre-operatively</p> <p>Exclusion criteria: people treated for ipsilateral haematomas with diversion of CSF within 6 months of presentation; those in whom surgery other than burr-hole evacuation was indicated; and those not needing surgical treatment because of size of CSDH or clinical status</p>
Interventions	<p>Participants were treated with 1 or 2 burr holes at the surgeon's discretion</p> <p>Group 1: no drains; participants treated with burr-hole craniostomy without closed-system drainage</p>

Singh 2014 (Continued)

Group 2: drains; participants treated by burr-hole craniostomy with closed-system drainage

Outcomes	<p>Primary outcome: recurrence risk; recurrence was defined as the occurrence of symptoms and signs attributable to an ipsilateral haematoma seen on a CT scan within 6 months of original drainage procedure All such symptomatic recurrences were re-operated</p> <p>Secondary outcomes: complications of surgery, mortality, GCS at discharge and at 2 weeks</p>
Notes	<p>Every participant received follow-up care for at least 6 months. The primary outcome was measured for all participants</p> <p>The study was conducted between January 2011 and June 2012</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "...were allocated randomly into two groups using random allocation software"
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Participants were followed up in the outpatient department, and the outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome was measured for all participants but 5 participants with drains and 4 without drains
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Tsutsumi 1997

Methods	Randomised controlled trial, single-centre (Japan)
Participants	118 participants (65 in Group 1, mean age 68 years; 53 in Group 2, mean age 69.7 years). Exclusion criteria: people with hygromas, infantile CSDH, calcified or ossified CSDH, and asymptomatic CSDH, because these conditions were considered to be different clinical entities
Interventions	<p>All participants had 1 burr hole inserted</p> <p>Group 1: no drains; burr-hole craniostomy without drainage</p> <p>Group 2: drains; burr-hole craniostomy with closed-system drainage. The drain (SL-C ventricular catheter; Sonne-Ika Co, Tokyo, Japan) placed within the cavity was connected to a ventricular drainage bag with an antireflux valve (Hanaco Medical Co, Saitama, Japan), which was placed on the bed for approximately 1 day, in the longest instance for 3 days</p>

Tsutsumi 1997 (Continued)

Outcomes	Primary outcome: recurrence risk; recurrence was defined as the reappearance of neurological symptoms within 6 months of surgery and an increase in the haematoma cavity volume on the operative side	
Notes	Every participant received follow-up care for at least 6 months The study was conducted between July 1992 and June 1996	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomized selection of surgical methods (that is, whether to use drainage or not) was decided by the toss of a coin
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome was measured for all participants
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found, but the important data (such as complications, outcome, and mortality) were not present
Other bias	Low risk	No other bias detected

Wakai 1990

Methods	Randomised controlled trial, single-centre (Japan) 33 males and 5 females	
Participants	38 participants (33 men and 5 women; Group 1 (n = 20): age range 52-84 years, mean age 70.8 years; Group 2 (n = 18), age range 42-84 years, mean 71.7 years) Exclusion criteria: people with severe disturbed states of consciousness or with coagulopathy at the time of admission	
Interventions	All participants had 1 burr hole inserted Group 1: no drains; burr-hole craniostomy without drainage Group B: drains; burr-hole craniostomy with closed-system drainage. The drain (SL-C ventricular catheter; Sonne-Ika Co, Tokyo, Japan) placed within the cavity was connected to a ventricular drainage bag with an antireflux valve (Hanaco Medical Co, Saitama, Japan), which was placed on the bed for 2-3 days	

Wakai 1990 (Continued)

Outcomes	Primary outcome: recurrence risk; recurrence was defined as reappearance of neurological symptoms, and increase in subdural cavity, and/or change in cavity density from low to iso-/high-density on CT scan	
	Secondary outcomes: complications of surgery, mortality and clinical recovery	
Notes	Every participant received follow-up care for 6 months	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Participants assigned sequentially according to admission to drains or no drains (using alternation)
Allocation concealment (selection bias)	Unclear risk	No details in text
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The nature of this intervention did not allow for masking of treatment allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessment was objective
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary and secondary outcomes were measured for all participants at 6 months
Selective reporting (reporting bias)	Low risk	All expected outcome data were reported and no selective reporting was found
Other bias	Low risk	No other bias detected

Abbreviations

CSDH; chronic subdural haematoma
 CSF; cerebro-spinal fluid
 CT; computed tomography
 GCS; Glasgow Coma Scale
 GOS; Glasgow Outcome Scale
 MRI; magnetic resonance imaging
 MRS; modified Rankin Scale

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Gurelik 2007	Not a randomized controlled trial
Hennig 1999	Not a randomized controlled trial
Kiymaz 2007	Not a randomized controlled trial, retrospective study
Lind 2003	Not a randomized controlled trial, retrospective study

External drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults (Review)

Study	Reason for exclusion
Okada 2002	Not a randomized controlled trial, retrospective study
Sarnivad 2011	Not a randomized controlled trial, retrospective study
Sindou 2010	Not a randomized controlled trial
Williams 2001	Not a randomized controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

[Shah 2014](#)

Methods	Randomised controlled trial, single-centre (Pakistan)
Participants	50 participants (25 in each group, age range 20-60 years, mean age 55.43 ± 5.16 years) with CSDH
Interventions	All participants had 1 burr hole inserted Group 1: no drains; participants treated by burr-hole craniostomy without closed-system drainage (one time drainage) Group 2: drains; participants treated by burr-hole craniostomy with closed-system drainage and the drain was removed after 48 h
Outcomes	Primary outcome: recurrence risk
Notes	Every participant received follow-up care for 6 months

Abbreviation

CSDH; chronic subdural haematoma

Characteristics of ongoing studies *[ordered by study ID]*

[NCT01785797](#)

Trial name or title	The effect of subdural drain placement after burr hole evacuation of chronic subdural haematomas on recurrence: a prospective randomised-controlled multi-centre study
Methods	Consecutive participants, 60 years old or above, diagnosed to have symptomatic CSDH and indicated for burr-hole operative drainage will be randomly allocated into one of two groups: 1) for intraoperative subdural drain placement (intervention group); or 2) not for drain placement (control group). Using web-based software, block randomisation with an allocation ratio of 1:1 will be conducted. Instructions to use or not to use a drain will be contained in sealed envelopes labelled with sequential study numbers
Participants	Inclusion criteria: <ol style="list-style-type: none"> 1. patients diagnosed to have symptomatic chronic subdural haematoma confirmed by a computed tomography or magnetic resonance imaging brain scan; 2. ethnic Chinese; 3. age ≥ 60 years; 4. reasonable expectation of completion of outcome measures at follow-up; 5. written informed consent

NCT01785797 (Continued)

Exclusion criteria: patients for whom the operating surgeon judges that drain placement is unsafe will be excluded from the study

Interventions	Intraoperatively, if the surgeon-in-charge judges that after burr-hole evacuation of the haematoma the participant's condition is unsafe for drain placement, the subject will be excluded from the study. Otherwise, randomisation will be performed at this juncture by the opening of the sealed envelope. The procedure involves placing a prefabricated silicone drain into the subdural space according to a standard protocol and will be removed on the second post-operative day at the bedside. Drainage is undertaken passively by hanging the collection bag at the bedside in a dependent position. In addition to general demographic, clinical and radiological presentation data, potential risk factors for recurrence will be documented. Serial CT brain scans will be arranged (before discharge, at 4 weeks and 6 months) and the occurrence of significant subdural haematoma recurrence requiring repeat operative drainage at 6 months will be recorded. Other outcome measures to be determined at regular time intervals for a total follow-up period of 6 months (upon discharge, at 4 weeks and 6 months) include: functional performance in terms of the extended GOS and MRS, added neurological deficit, death and other surgery-related complications. All outcomes will be documented by the trial investigators or by the responsible clinician. The data obtained will be analyzed according to the principle of intention-to-treat
Outcomes	<p>Primary outcomes: significant recurrent chronic subdural haematoma i.e. requiring repeat operative drainage at 6 months after the primary operation (time frame: 6 months after primary burr-hole evacuation of chronic subdural haematoma)</p> <p>Secondary outcomes: functional performance in terms of the Extended GOS, added neurological deficit, surgery-related complications, death, MRS</p>
Starting date	June 2013
Contact information	Peter YM Woo, FRCS (SN) 852+ 3517 2275 ext 2275 peterymwoo@gmail.com
Notes	<p>ClinicalTrials.gov Identifier: NCT01785797</p> <p>The ethics committee approval detail is not provided</p>

Abbreviations

CSDH; chronic subdural haematoma

CT; computed tomography

GOS; Glasgow Outcome Scale

MRS; modified Rankin Scale

DATA AND ANALYSES
Comparison 1. Comparison of drains versus no drains

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Recurrence	9	968	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.32, 0.61]
1.1 Two holes	3	306	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.26, 0.80]
1.2 One hole	2	156	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.05, 0.56]
1.3 One or two holes	4	506	Risk Ratio (M-H, Fixed, 95% CI)	0.52 [0.34, 0.79]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Complications	7	710	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.77, 1.72]
3 Mortality	5	539	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.45, 1.33]
4 Poor functional outcome	5	490	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.44, 1.05]
5 Sensitivity analysis of recurrence	7	802	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.22, 0.50]

Analysis 1.1. Comparison 1 Comparison of drains versus no drains, Outcome 1 Recurrence.

Analysis 1.2. Comparison 1 Comparison of drains versus no drains, Outcome 2 Complications.

Analysis 1.3. Comparison 1 Comparison of drains versus no drains, Outcome 3 Mortality.

Analysis 1.4. Comparison 1 Comparison of drains versus no drains, Outcome 4 Poor functional outcome.

Analysis 1.5. Comparison 1 Comparison of drains versus no drains, Outcome 5 Sensitivity analysis of recurrence.

APPENDICES

Appendix 1. Search strategies

Cochrane Injuries Group Specialised Register

Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library)

```
#1MESH DESCRIPTOR Hematoma, Subdural, Intracranial
#2MESH DESCRIPTOR Intracranial Hemorrhage, Traumatic
#3(chronic near1 sub?dural):TI,AB,KY
#4(haematoma* or hematoma* or haemorrhag* or hemorrhag* or bleed*):TI,AB,KY
#5(subepidural or pachymening* or extracran*):TI,AB,KY
#6MESH DESCRIPTOR hematoma, subdural
#7MESH DESCRIPTOR hematoma, subdural, chronic
#8#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
#9MESH DESCRIPTOR Drainage
#10(burr hole drainage):TI,AB,KY
#11(double burr hole drainage):TI,AB,KY
#12(drainage adj1 system*):TI,AB,KY
#13(gravity adj1 drainage):TI,AB,KY
#14(closed-system drainage):TI,AB,KY
#15(closed-suction drainage):TI,AB,KY
#16#9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15
#17#8 AND #16
#18* NOT INMEDLINE NOT INEMBASE
#19#17 AND #18
```

Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid OLDMEDLINE(R)

```
1. randomi?ed.ab,ti.
2. randomized controlled trial.pt.
3. controlled clinical trial.pt.
4. placebo.ab.
5. clinical trials as topic.sh.
6. randomly.ab.
7. trial.ti.
8. Comparative Study/
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
```

10. (animals not (humans and animals)).sh.
11. 9 not 10
12. hematoma, subdural/ or hematoma, subdural, chronic/
13. (chronic adj1 sub?dural).mp.
14. (haematoma* or hematoma* or haemorrhag* or hemorrhag* or bleed*).ab,ti.
15. (subepidural or pachymening* or extracran*).mp.
16. Intracranial Hemorrhage, Traumatic/
17. Hematoma, Subdural, Intracranial/
18. 12 or 13 or 14 or 15 or 16 or 17
19. Drainage/
20. burr hole drainage.mp.
21. (drainage adj1 (procedure* or pressure)).mp.
22. drain*.mp.
23. single burr hole drainage.mp.
24. double burr hole drainage.mp.
25. (drainage adj1 system*).mp.
26. (gravity adj1 drainage).mp.
27. closed-system drainage.mp.
28. closed-suction drainage.mp.
29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. 18 and 29
31. 11 and 30

Embase Classic + Embase

1. hematoma, subdural/ or hematoma, subdural, chronic/
2. (chronic adj1 sub?dural).ab,ti.
3. (haematoma* or hematoma* or haemorrhag* or hemorrhag* or bleed*).ab,ti.
4. (subepidural or pachymening* or extracran*).ab,ti.
5. Intracranial Hemorrhage, Traumatic/
6. Hematoma, Subdural, Intracranial/
7. 1 or 2 or 3 or 4 or 5 or 6
8. Drainage/
9. burr hole drainage.mp.
10. (drainage adj1 (procedure* or pressure)).mp.
11. drain*.ab,ti.
12. single burr hole drainage.mp.
13. double burr hole drainage.mp.
14. (drainage adj1 system*).mp.
15. (gravity adj1 drainage).mp.
16. closed-system drainage.mp.
17. closed-suction drainage.mp.
18. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 7 and 18
20. exp Randomized Controlled Trial/
21. exp controlled clinical trial/
22. exp controlled study/
23. comparative study/
24. randomi?ed.ab,ti.
25. placebo.ab.
26. *Clinical Trial/
27. exp major clinical study/
28. randomly.ab.
29. (trial or study).ti.
30. 20 or 21 or 22 or 24 or 25 or 26 or 27 or 28 or 29
31. exp animal/ not (exp human/ and exp animal/)
32. 30 not 31
33. 19 and 32
34. remove duplicates from 33

PubMed

((publisher[sb] NOT pubstatusnihms))) AND (((((((("Comparative Study"[Publication Type]) OR "Randomized Controlled Trial"[Publication Type]) OR "Controlled Clinical Trial"[Publication Type])) OR (((((((randomized[Title/Abstract]) OR randomised[Title/

Abstract]) OR placebo[Title/Abstract]) OR randomly[Title/Abstract]) OR trial[Title/Abstract]) OR groups[Title/Abstract]) OR group[Title/Abstract]) NOT (("Animals"[Mesh]) NOT ("Animals"[Mesh] AND "Humans"[Mesh])) AND (((((((((((burr hole drainage[Title/Abstract]) OR drainage procedure*[Title/Abstract]) OR drainage pressure[Title/Abstract]) OR single burr hole drainage[Title/Abstract]) OR double burr hole drainage[Title/Abstract]) OR drainage system[Title/Abstract]) OR gravity drainage[Title/Abstract]) OR "closed system drainage"[Title/Abstract]) OR "closed suction drainage"[Title/Abstract]) OR "Drainage"[Mesh:noexp])) AND (((((((("Intracranial Hemorrhage, Traumatic"[Mesh:noexp]) OR "Hematoma, Subdural, Intracranial"[Mesh])) OR subepidural[Title/Abstract]) OR pachymening*[Title/Abstract]) OR extracran*[Title/Abstract]) OR (haematoma*[title/abstract] OR hematoma*[title/abstract] OR haemorrhag*[title/abstract] OR hemorrhag*[title/abstract] OR bleed*[title/abstract])) OR ((chronic subdural[Title/Abstract]) OR chronic sub-dural[Title/Abstract])) OR (((("Hematoma, Subdural"[Mesh:noexp]) OR "Hematoma, Subdural, Chronic"[Mesh]) OR "Intracranial Hemorrhage, Traumatic"[Mesh:noexp]) OR "Hematoma, Subdural, Intracranial"[Mesh]))))

ISI Web of Science: Science Citation Index Expanded (SCI-EXPANDED) & Conference Proceedings Citation Index- Science (CPCI-S)

#12#11 AND #10 AND #6
11TS=(drainage) OR TS=("burr hole drainage") OR TS=("closed-system drainage") OR TS=("closed-suction drainage")
10#9 OR #8 OR #7
9TS=(subepidural or pachymening* or extracran*)
8TS=(haematoma* or hematoma* or haemorrhag* or hemorrhag* or bleed*)
7TS=("subdural hematoma") OR TS=("subdural haematoma")
6#5 AND #4
5TS=(human*)
4#3 OR #2 OR #1
3TS=((singl* OR doubl* OR trebl* OR tripl*) SAME (blind* OR mask*))
2TS=(controlled clinical trial OR controlled trial OR clinical trial OR placebo)
1TS=(randomised OR randomized OR randomly OR random order OR random sequence OR random allocation OR randomly allocated OR at random OR randomized controlled trial)

Clinicaltrials.gov

(chronic subdural haematoma OR CSDH) [DISEASE] AND (burr-hole OR burr hole) [TREATMENT]

WHO International Clinical Trials Registry Platform

Condition: chronic AND subdural AND haematoma

Appendix 2. Chinese database search strategies

The Chinese Biomedical Database (CBM)

#1 (("血肿, 硬膜下, 慢性"[不加权:扩展]) OR "血肿, 硬膜下"[不加权:扩展]) OR "颅内出血, 创伤性"[不加权:扩展]
#2 (((("慢性硬膜下血肿"[中文标题:智能]) OR "硬膜下血肿"[中文标题:智能]) OR "硬膜下"[中文标题:智能]) OR "血肿"[中文标题:智能])
#3 "引流术"[不加权:扩展]
#4 (((((((("钻孔"[摘要:智能]) OR "钻孔引流"[摘要:智能]) OR "锥孔"[摘要:智能]) OR "引流"[摘要:智能]) OR "冲洗"[摘要:智能]) OR "负压引流"[摘要:智能]) OR "闭式引流"[摘要:智能]) OR "外引流"[摘要:智能])
#5 (("随机对照试验"[不加权:扩展]) OR "随机对照试验(主题)"[不加权:扩展]) OR "随机对照试验(主题)"[不加权:扩展]
#6 (((("随机对照"[摘要:智能]) OR "随机"[摘要:智能]) OR "对照研究"[摘要:智能]) OR "对照"[摘要:智能])
#7 ((#1) OR (#2))
#8 ((#3) OR (#4))
#9 (#5) OR (#6))
#10 (((#7) AND (#8))) AND (#9))

The Chinese National Knowledge Infrastructure (CNKI)

((TI='慢性硬膜下血肿' OR TI='硬膜下血肿' OR TI='硬膜下出血' OR TI='硬膜下') AND (TI='单孔' OR TI='双孔' OR TI='钻孔' OR AB='负压引流' OR AB='负压封闭引流' OR AB='钻孔引流' OR TI='锥孔' OR TI='引流' OR TI='冲洗' OR TI='闭式引流')) AND (AB='随机对照试验' OR AB='随机对照' OR AB='随机' OR AB='对照' OR AB='对照研究')

China Online Journals (WanFang Medical Online)

((Title=慢性硬膜下血肿 or Title=硬膜下血肿 or Title=硬膜下出血 or Title=硬膜下) and (单孔 or 双孔 or 钻孔 or 锥孔 or 引流 or 冲洗 or 闭式引流)) and (随机 or 对照)

CONTRIBUTIONS OF AUTHORS

DP and YZ assessed the eligibility of identified studies and extracted data from included studies. DP entered data, performed analysis, and wrote the first draft of the review. DP and YZ commented on the paper.

DECLARATIONS OF INTEREST

DP: none known

YZ: none known

SOURCES OF SUPPORT

Internal sources

- The Second Affiliated Hospital of Zhejiang University School of Medicine and Zhejiang Provincial People's Hospital, China.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Review title

Changed from 'Drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults' in the protocol to 'External drains versus no drains after burr-hole evacuation for the treatment of chronic subdural haematoma in adults' for the review.

Search methods

Since the search methods were agreed for the protocol the register, Current Controlled Trials (www.controlled-trials.com/mrct/) service is now under review. For this reason it has not been searched however searching the International Clinical Trials Registry Platform (who.int/ictrp/en/) should have retrieved most registered trials.

We searched PubMed to retrieve references that were not indexed in MEDLINE or Embase.

INDEX TERMS

Medical Subject Headings (MeSH)

Drainage [adverse effects] [instrumentation] [*methods] [mortality]; Dura Mater [surgery]; Hematoma, Subdural, Chronic [*therapy]; Osteotomy [methods]; Randomized Controlled Trials as Topic; Recurrence; Secondary Prevention [instrumentation] [methods]; Skull [surgery]

MeSH check words

Adult; Humans