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[Intervention Review]

Immediate versus delayed postpartum insertion of contraceptive implant for contraception

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ABSTRACT

Background

The spacing of pregnancies has a positive impact on maternal and newborn health. The progestin contraceptive implant, which is a long-acting, reversible method of contraception, has a well-established low failure rate that is compatible with tubal sterilization. The standard provision of contraceptive methods on the first postpartum visit may put some women at risk of unintended pregnancy, either due to loss to follow-up or having sexual intercourse prior to receiving contraception. Therefore, the immediate administration of contraception prior to discharge from the hospital that has high efficacy may improve contraceptive prevalence and prevent unintended pregnancy.

Objectives

To compare the initiation rate, effectiveness, and side effects of immediate versus delayed postpartum insertion of implant for contraception.

Search methods

We searched for eligible studies up to 28 October 2016 in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and POPLINE. We examined review articles and contacted investigators. We also checked registers of ongoing clinical trials, citation lists of included studies, key textbooks, grey literature, and previous systematic reviews for potentially relevant studies.

Selection criteria

We sought randomised controlled trials (RCTs) that compared immediate postpartum versus delayed insertion of contraceptive implant for contraception.

Data collection and analysis

Two review authors (JS, YW) independently screened titles and abstracts of the search results, and assessed the full-text articles of potentially relevant studies for inclusion. They extracted data from the included studies, assessed risk of bias, compared results, and resolved disagreements by consulting a third review author (PL or SK). We contacted investigators for additional data, where possible. We computed the Mantel-Haenszel risk ratio (RR) with 95% confidence interval (CI) for binary outcomes and the mean difference (MD) with 95% CI for continuous variables.

Main results

Three studies that included 410 participants met the inclusion criteria of the review. We did not identify any ongoing trials. Two included studies were at low risk of selection, attrition, and reporting biases, but were at high risk of performance and detection biases due to the inability to blind participants to the intervention. One included study was at high risk of attrition bias. The overall quality of the evidence for each comparison ranged from very low to moderate; the main limitations were risk of bias and imprecision.

Initiation rate of contraceptive implants at the first postpartum check-up visit was significantly higher in the immediate insertion group than in the delayed insertion group (RR 1.41, 95% CI 1.28 to 1.55; three studies, 410 participants; *moderate quality evidence*).

There appeared to be little or no difference between the groups in the continuation rate of contraceptive implant used at six months after insertion (RR 1.02, 95% CI 0.93 to 1.11; two studies, 125 participants; *low quality evidence*) or at 12 months after insertion (RR 1.04; 95% CI 0.81 to 1.34; one study, 64 participants; *very low quality evidence*).

Women who received an immediate postpartum contraceptive implant insertion had a higher mean number of days of abnormal vaginal bleeding within six weeks postpartum (MD 5.80 days, 95% CI 3.79 to 7.81; one study, 215 participants; *low quality evidence*) and a higher rate of other side effects in the first six weeks after birth (RR 2.06, 95% CI 1.38 to 3.06; one study, 215 participants; *low quality evidence*) than those who received a delayed postpartum insertion. There appeared to be little or no difference between the groups in heavy, irregular vaginal bleeding or associated severe cramping within 12 months (RR 1.01, 95% CI 0.72 to 1.44, one study, 64 participants; *very low quality evidence*).

It was unclear whether there was any difference between the groups in scores for participant satisfaction on a 0-10 scale (MD -0.40, 95% CI -1.26 to 0.46, *low quality evidence*), or in rates of unintended pregnancy (RR 1.82, 95% CI 0.38 to 8.71, 1 RCT, 64 women, *very low quality evidence*) at 12 months, or in rate of breastfeeding rate at six months (RR 2.01, 95% CI 0.72 to 5.63, 1 RCT, 64 women, *very low quality evidence*) rate did not differ significantly between the groups.

Authors' conclusions

Evidence from this review indicates that the rate of initiation of contraceptive implant at the first postpartum check-up visit was higher with immediate postpartum insertion than with delayed insertion. There appeared to be little or no difference between the groups in the continuation rate of contraceptive implant use at 6 months. It was unclear whether there was any difference between the groups in continuation of contraceptive use at 12 months or in the unintended pregnancy rate at 12 months.

PLAIN LANGUAGE SUMMARY

Inserting a contraceptive implant soon after childbirth

Review question

Cochrane authors compared the initiation rate, effectiveness, and side effects of insertion of a contraceptive implant (implant for birth control) soon after childbirth versus delayed insertion at postpartum visit.

Background

The spacing of pregnancies has a positive impact on health of both pregnant women and newborns. The contraceptive implant is a highly effective progestin-only method of birth control. Normally, a contraceptive implant is provided at the first (usually at six weeks) postpartum visit. However, some women do not come back, or have sex before this check-up visit. The insertion of a contraceptive implant after childbirth but before hospital discharge is worthy of consideration; it is convenient in terms of time and place, and may increase the number of women that use this method.

Study characteristics

We searched for randomised studies up to 28 October 2016. We looked at whether insertion of contraceptive implant soon after childbirth or when women come back for the first postpartum check-up affected use of this contraception method. We included three studies with a total of 410 women.

Key results

Use of a contraceptive implant was higher when it was applied right after childbirth than when it was applied four to six weeks later. There appeared to be little or no difference between the groups in the continuation rate of contraceptive implant use at 6 months. It was unclear whether there was any difference between the groups in continuation of contraceptive use at 12 months or in the unintended pregnancy rate at 12 months.

Although vaginal bleeding and other adverse effects in the first six weeks after birth including nausea, hair loss, hirsutism, headache, and acne seem to be higher in women that receive this method a few days after childbirth rather than four to six weeks later, this finding however cannot be definitely concluded as all participants knew the nature of the intervention they received (were not blinded) and the

reports of these adverse effects were not objectively assessed. It was unclear whether there was any difference between the groups at 12 months in heavy, irregular vaginal bleeding or associated severe cramping, rates of unintended pregnancy, or in measures of participants' satisfaction. Nor was it clear whether there was any difference in breastfeeding rates at 6 months. The included studies were conducted in the USA, and generalisation of these findings to other population or settings should be applied with caution.

Quality of the evidence

Overall, the quality of the evidence was moderate to very low. The main limitations were imprecision and risk of bias (related to lack of blinding and to attrition). Further good quality, well-designed randomised controlled trials will provide additional information.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Immediate postpartum insertion compared with delayed insertion of contraceptive implant for contraception

Immediate postpartum insertion compared with delayed insertion of contraceptive implant for contraception

Participant or population: postpartum women who desire a contraceptive implant for contraception

Settings: hospitals in United States

Intervention: immediate postpartum insertion

Comparison: delayed insertion

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Delayed insertion	Immediate insertion				
Rate of initiation of contraceptive implants	69 per 100	97 per 100 (88 to 100)	RR 1.41 (1.28 to 1.55)	410 (3 studies)	⊕⊕⊕⊖ moderate ¹	
Continuation rate at 6 months	90 per 100	92 per 100 (84 to 100)	RR 1.02 (0.93 to 1.11)	125 (2 studies)	⊕⊕⊕⊖ low ²	
Continuation rate at 12 months	78 per 100	81 per 100 (63 to 100)	RR 1.04 (0.81 to 1.34)	64 (1 study)	⊕⊕⊖⊖ very low ^{2,4}	
Side effects: Abnormal vaginal bleeding within 6 weeks post partum	Mean 22.4	Mean 5.80 higher (95% CI 3.79 higher to 7.81 higher)	MD 5.80 (3.79 to 7.81)	215 (1 study)	⊕⊕⊖⊖ low ^{1,3}	
Side effects: Other side effects within 6 weeks	23 per 100	47 per 100 (32 to 70)	RR 2.06 (1.38 to 3.06)	215 (1 study)	⊕⊕⊖⊖ low ^{1,3}	
Side effects: Heavy, irregular vaginal bleeding or associated severe cramping within 12 months	67 per 100	68 per 100 (48 to 96)	RR 1.01 (0.72 to 1.44)	64 (1 study)	⊕⊕⊖⊖ very low ^{2,4}	
Participants' satisfaction at 12 months	Mean 8.7	Mean 0.40 lower	MD -0.40 (-1.26 to 0.46)	64	⊕⊕⊖⊖ low ^{1,4}	

		(95% CI 1.26 lower to 0.46 higher)		(1 study)	
Unintended pregnancy rate at 12 months	7 per 100	13 per 100 (3 to 61)	RR 1.82 (0.38 to 8.71)	64 (1 study)	⊕⊕⊕⊖ very low^{2,4}
Breastfeeding at six months post-partum	15 per 100	30 per 100 (11 to 84)	RR 2.01 (0.72 to 5.63)	64 (1 study)	⊕⊕⊕⊖ very low^{2,4}

*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% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

Abbreviations: CI: confidence interval; RR: risk ratio; MD: mean difference.

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.

¹Downgraded one level owing to serious imprecision (small number of participants)

²Downgraded two levels owing to very serious imprecision (small number of participants, and the CI includes appreciable benefit and harm).

³Downgraded one level owing to serious risk of assessment bias.

⁴Downgraded one level owing to serious risk of attrition bias.

BACKGROUND

Description of the condition

Traditionally, the first postpartum visit is scheduled to be at six weeks after childbirth (Speroff 2008). This visit is either to assess the recovery of the mother after childbirth or to address the contraceptive needs going forward. Although the postpartum visit is an ideal time to discuss and implement family planning services, there is a notably high default rate from postpartum appointments, particularly among adolescent mothers. This results in delayed or missed counselling opportunities about an appropriate contraception method (Moore 2015; Nkwabong 2015). In addition, nearly half of women have reported to have had unprotected vaginal sexual intercourse before attending a six-week postpartum visit (Brito 2009; Chaovitsaree 2012). Delayed initiation of contraception after childbirth and having unprotected sexual intercourse before attending postpartum clinic can lead to an unintended pregnancy (Wilson 2011). As unintended pregnancy may have a negative impact on newborn and maternal health (Fraser 1995; Singh 2010; Finer 2011), designing effective contraception practices for reducing unintended pregnancy among women who are at heightened risk is of utmost importance.

Description of the intervention

Provision of contraception usually occurs six weeks postpartum. However, a study conducted in the USA indicated that only 41% of women received contraceptives within 90 days after delivery (Thiel de Bocanegra 2013). This figure is similar to the reported results from low- and middle-income countries (Moore 2015; Nkwabong 2015). Therefore immediate administration of effective contraception is worth considering.

Contraceptive implants are a long-acting, reversible, progestin-only method. Currently, two types of progestin are used as active ingredients in contraceptive implants, including levonorgestrel and etonogestrel. The primary mechanism of action of the implant is to suppress ovulation by altering the hypothalamic–pituitary–ovarian axis. The other mechanisms are to thicken cervical mucus and to alter the endometrial lining (ACOG 2011).

Contraceptive implants are extremely effective and safe. This contraceptive method offers up to three to five years of reliable pregnancy prevention once inserted. The typical-use failure rate is only 0.05% (ACOG 2011). The satisfaction rate of the implant is reported to be high. Approximately 80% of users reported satisfaction with implant leading to a high continuation rate (Peipert 2011).

Based on its high efficacy and safety, contraceptive implants are suitable for nearly all women that need contraception (ACOG 2012; WHO 2015). The common side effects of contraceptive implants include amenorrhoea, irregular menstrual bleeding, spotting, sore breasts, headache, and weight gain. However, most side effects are mild, well-tolerated, and self-resolve within the first few months of use, and women should receive counselling in order to understand the side effects.

How the intervention might work

There is an increased risk of unintended pregnancy among women who have delayed initiation of contraception after childbirth or unprotected sexual intercourse before attending

a postpartum clinic. Immediate postpartum provision of highly effective contraception, including intrauterine devices (IUDs) and contraceptive implant, has been proposed (ACOG 2011).

Based on a recent Cochrane systematic review, immediate postpartum insertion of IUDs appears to be safe and effective (Lopez 2015). Advantages of this practice include high motivation and convenience for both postpartum women and providers. However, the expulsion rate of IUDs inserted immediately postpartum is slightly higher than in women that have deferred insertion of IUDs (Lopez 2015).

Immediate postpartum provision of the contraceptive implant has no significant negative impact on outcomes regarding maternal health and infant weight gain (Brito 2009). The World Health Organization's (WHO's) medical eligibility criteria for contraceptive use support contraceptive implant insertion prior to hospital discharge regardless of lactating status (Whaley 2015; WHO 2015). The side effects of immediate postpartum insertion of contraceptive implants also appear to be similar to that of interval insertion (Ireland 2014). Additionally, the three-year continuation rate of this method is as high as 66% when contraceptive implants are inserted immediately postpartum, which emphasizes a high level of women's satisfaction with this practice (Wilson 2014).

Why it is important to do this review

Immediate postpartum insertion of a contraceptive implant could be a promising choice of timing of contraceptive method initiation. This is quite crucial for postpartum women who are at high risk of missing the six-week postpartum visit, or of having early unprotected intercourse after childbirth, or both.

However, to our knowledge, there has been no systematic review to date that has evaluated the effectiveness and safety of immediate postpartum insertion of contraceptive implant for contraception.

OBJECTIVES

To compare the initiation rate, effectiveness, and side effects of immediate versus delayed postpartum insertion of implant for contraception.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs), irrespective of blinding, language, publication status, or sample size. We did not include controlled clinical trials (CCTs) that used non-random methods of assigning participants to treatment, such as by alternation, by birth date, or by medical record number, as they may be subject to high risk of bias.

Types of participants

Postpartum women who requested a reversible contraceptive method and were recruited before hospital discharge.

Types of interventions

Immediate postpartum insertion of contraceptive implant (after delivery to before hospital discharge) compared to delayed post-

partum insertion (during postpartum visit after hospital discharge), which is often referred to as standard or interval insertion.

Types of outcome measures

Primary outcomes

- Rate of contraceptive implant initiation at the first postpartum check-up visit.

Secondary outcomes

- Continuation rate at 6, 12, and 24 months after delivery.
- Side effects, such as abnormal vaginal bleeding.
- Participant satisfaction.
- Rate of pregnancy at 6, 12, and 24 months after delivery.
- Unintended pregnancy rate at 6, 12, and 24 months after delivery.
- Rapid repeat pregnancy (defined as pregnancy onset within two years of the previous pregnancy (Baldwin 2013)).
- Breastfeeding at six months postpartum

Search methods for identification of studies

Electronic searches

We searched the following electronic databases;

- The Cochrane Central Register of Controlled Trials (CENTRAL, 2016, issue 10);
- MEDLINE (1946 to October week 4, 2016)
- Embase (1980 to October 2016),
- POPLINE (1970 to October 2016)

We have provided the search strategies in [Appendix 1](#).

Searching other resources

We checked the citation lists of included studies, key textbooks, and systematic reviews for potentially relevant references. We searched the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (<http://www.who.int/ictpr/en/>) and ClinicalTrials.gov to identify ongoing trials. We applied modified versions of the same search strategy to check the following databases for grey literature: OpenGrey, GreyNet, Scirus, Social Care Online, National Research Register, NIHR portfolio database, and Index to theses.

Data collection and analysis

Selection of studies

Before examining the identified trials for possible inclusion, we developed and piloted a data collection form, as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We downloaded all titles and abstracts retrieved by electronic searching to EndNote (EndNote 2015), a reference management database, and removed duplicates. Two review authors, JS and YW, independently screened the titles and abstracts of the remaining studies. We excluded studies that clearly did not meet the inclusion criteria. We obtained full-text copies of potentially relevant studies. Two review authors, JS and YW, independently assessed the eligibility of the retrieved reports/publications. We resolved any disagreement through discussion or, if required, we consulted a third review author (PL). We identified

and intended to collate multiple reports of the same study so that each study, rather than each report, was the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009) and a 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors, JS and YW, independently extracted study characteristics and outcome data from included studies using a piloted data collection form. We noted in the 'Characteristics of included studies' table if the included trials did not report outcome data in a usable way. We then contacted the trial authors for further information. We resolved disagreements by consensus or by involving a third review author (PL or SK). One review author, ML, entered data into Review Manager 5 (RevMan 5) (RevMan 2014). We double-checked whether data is entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (PL or SK) checked all study characteristics for accuracy against the trial report.

For included studies, we extracted the following data.

- Author, year of publication, and journal citation (including language).
- Country.
- Setting.
- Inclusion and exclusion criteria.
- Study design and methodology.
- Study population.
- Study outcomes and their related summary statistics.

Assessment of risk of bias in included studies

We assessed and reported on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), which recommends the explicit reporting of the following individual elements for RCTs.

- Selection bias: random sequence generation and allocation concealment.
- Performance bias: blinding of participants and personnel (participants and treatment providers).
- Detection bias: blinding of outcome assessors.
- Attrition bias: incomplete outcome data.
- Reporting bias: selective reporting of outcomes.

Two review authors, JS and YW, independently applied the 'Risk of bias' tool to each included study and resolved differences by discussion or by consulting a third review author (PL or ML). We judged each item as at either 'high', 'low', or 'unclear' risk of bias, as set out in the criteria provided by Higgins 2011, and provided a quote from the study report or a statement as justification for the judgement for each item in the 'Risk of bias' table. We summarized the results in both a 'Risk of bias' graph and a 'Risk of bias' summary. When we interpreted treatment effects and meta-analyses, we took into account the risk of bias for the studies that contributed to that outcome. Where information on risk of bias was related to unpublished data or correspondence with a trial author, we noted this in the 'Risk of bias' table.

Measures of treatment effect

We used the following measures of the effect of treatment.

- For dichotomous outcomes, such as the rate of contraceptive implant initiation, we used number of events and number of participants assessed for both the intervention and comparison groups to calculate the risk ratio (RR) and 95% confidence interval (CI).
- For continuous outcomes, such as satisfaction rate, we used mean, standard deviation (SD), and the number of participants assessed for both the intervention and comparison groups to calculate mean difference (MD) with 95% CI.

Unit of analysis issues

We intended to include studies where individual postpartum women were randomised and cluster-randomised studies where, for example, the hospital was the unit of randomisation. However, we did not find any cluster randomised studies that met the review inclusion.

Dealing with missing data

We did not impute any missing outcome data and we tried to contact the trial authors for missing data.

Assessment of heterogeneity

We assessed heterogeneity by visual inspection of the forest plots. We also assessed statistical heterogeneity in each meta-analysis using the I^2 statistic and χ^2 test. We regarded heterogeneity as substantial if the I^2 statistic value was greater than 50%, or there was a low P value (less than 0.10) in the χ^2 test for heterogeneity (Deeks 2001).

Assessment of reporting biases

As only three RCTs met the review inclusion criteria, we were unable to construct funnel plots to determine the possibility of publication bias.

Data synthesis

We undertook meta-analysis for all the outcomes where suitable data were available. We described in narrative skewed data reported as medians and interquartile ranges.

Using RevMan 5 we performed statistical analyses (RevMan 2014). We used a fixed-effect model to combine data where it is reasonable to assume that studies were estimating the same underlying treatment effect i.e. where studies were examining the same intervention, and we judged the studies' populations and methods to be sufficiently similar. If there was unexplained clinical heterogeneity sufficient to expect that the underlying treatment effects differed between studies, or if substantial statistical heterogeneity sufficient to expect that the underlying treatment effects differed between studies, or if we detected substantial statistical heterogeneity, we used a random-effects meta-analysis to produce an overall summary if we considered an average treatment effect across trials to be clinically meaningful. We used the random-effects meta-analysis, treated the pooled treatment effect as the average range of possible treatment effects, and discussed the clinical implications of treatment effects differing between studies. If the average treatment effect was not clinically meaningful, we did not intend to combine study results. If we used

random-effects analyses, we presented the results as the pooled treatment effect with 95% CIs, and the estimates of the T^2 and I^2 statistic (DerSimonian 1986). We prepared a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). For the data that we were unable to pool for meta-analysis, we conducted a narrative synthesis of the results.

Subgroup analysis and investigation of heterogeneity

We planned to perform subgroup analyses according to age of participants (teenagers versus non-teenagers) and population differences (high-income versus low- and middle-income countries). We did not perform these subgroup analyses due to the limited number of included studies.

Sensitivity analysis

We planned to perform sensitivity analyses in order to determine the impact of the following factors on effect size:

- Repeating the analysis excluding unpublished studies (if any).
- Repeating the analysis excluding trials rated as 'high' or 'unclear' for risk of selection bias

There were too few studies to perform these sensitivity analyses.

Overall quality of the evidence: 'Summary of findings' table

Two review authors working independently prepared a 'Summary of findings' table, with disagreements were resolved by consensus. The following outcomes were reported on the table: rate of initiation of contraceptive implants, continuation rate at 6 months, continuation rate at 12 months, side-effects: abnormal vaginal bleeding within 6 weeks postpartum, side effects other than abnormal vaginal bleeding, participant's satisfaction, unintended pregnancy rate and breastfeeding at six months postpartum.

We used the GRADE approach (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the evidence (GRADEproGDT 2014). We used methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We justified all decisions to downgrade the quality of evidence, using footnotes.

RESULTS

Description of studies

Results of the search

We identified 817 references from the combined searches. After we removed 323 duplicated references, we screened the titles and abstracts of 494 references and discarded 481 references as they obviously did not meet the review inclusion criteria. Of the 13 studies that potentially met the review inclusion criteria, we excluded 10 studies after we reviewed the full texts of these studies (see the 'Characteristics of excluded studies' table), thereby leaving three studies that met the inclusion criteria of this review (Phemister 1995; Gurtcheff 2011; Bryant 2016); see the 'Characteristics of included studies' table). We checked the reference lists of included studies, key textbooks, and systematic reviews for potentially relevant references but found no relevant

studies. We did not find any ongoing trials. [Figure 1](#) displays the PRISMA flow diagram.

Figure 1. Study flow diagram.

Included studies

We included three randomised controlled trials (RCTs) ([Phemister 1995](#); [Gurtcheff 2011](#); [Bryant 2016](#)), and presented the details of the included studies in the 'Characteristics of included studies' table.

[Phemister 1995](#) was conducted in the USA from June 1992 to February 1993. Participants were women who intended to

use a contraceptive implant for postpartum contraception, had vaginal births at gestational age of 34 weeks or more, and did not have anaemia. Most women who participated in this study were black (understood to be African-American). Participants in the intervention group received immediate postpartum insertion of the levonorgestrel contraceptive implant (Norplant®, Wyeth-Ayerst, Philadelphia) between day 1 to day 3 after delivery.

Participants in the control group received the same contraceptive method between four to six weeks after delivery. Reported outcomes included postpartum bleeding evaluated by the change of haemoglobin level and vaginal bleeding reported in the participant diary; postpartum contraceptive prevalence; and side effects that included nausea, hair loss, hirsutism, headache, and acne. The outcomes were evaluated during the visit scheduled at four to six weeks after delivery.

[Gurtcheff 2011](#) was conducted in the USA from January to October 2009. Most participants were Hispanic. This study recruited 69 healthy peripartum women with healthy term newborns, who intended to breast feed, and desired a contraceptive implant. The contraceptive implant used was a single-rod etonogestrel (Implanon®, Schering-Plough). Participants allocated to the intervention group received immediate insertion of the etonogestrel contraceptive implant within three days after delivery. Participants assigned to the control group received the same contraceptive method four to eight weeks after delivery. The study outcomes were time to lactogenesis, lactational failure, postpartum contraceptive prevalence, participant-reported vaginal bleeding, and breast milk creatinocrit.

[Bryant 2016](#) was conducted in USA from August 2012 to April 2015. Most participants were Hispanic or Latino. The trial included postpartum women aged 14 to 24 years who desired to use the etonogestrel contraceptive implant. Participants allocated to

intervention group received the contraceptive implant prior to discharge from the hospital. Participants in control group received the same contraceptive method at four to six weeks postpartum visit. The study outcomes were contraceptive prevalence at the first postpartum check-up visit, rate of contraceptive implant use at 12 months, participants' satisfaction; abnormal bleeding patterns, breastfeeding, and unintended pregnancy rate.

Excluded studies

After assessing the full texts of 13 potentially eligible studies, we excluded 10 studies because of the following main reasons (see the 'Characteristics of excluded studies' table).

- Six studies were not RCTs or CCTs ([Shabaan 1985](#); [Taneepanichkul 2001](#); [Tocce 2012](#); [Ireland 2014](#); [Wilson 2014](#); [Garipey 2015](#)).
- Two studies compared immediate postpartum insertion of contraceptive implant as compared to no treatment ([Brito 2012](#); [Bragy 2015](#)).
- Two studies compared immediate postpartum insertion of contraceptive implant as compared with depot medroxyprogesterone acetate ([Brito 2009](#); [Pentickly 2013](#)).

Risk of bias in included studies

[Figure 2](#) and [Figure 3](#) summarize the 'Risk of bias' items presented as percentages across all included studies.

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

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): primary outcome	Blinding of participants and personnel (performance bias): secondary outcomes	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bryant 2016	+	+	+	-	?	-	+	?
Gurtcheff 2011	+	+	+	-	?	+	+	?
Phemister 1995	+	+	+	-	?	+	+	?

Allocation

Random sequence generation and allocation concealment

The three included studies randomly allocated participants to the comparison groups using adequate methods for sequence generation and concealment of allocation (Phemister 1995;

Gurtcheff 2011; Bryant 2016). We therefore judged all three studies as at low risk of this bias.

Blinding

Although the timing of contraceptive implant insertion could not be blinded, we judged all three included studies as at low risk

of performance and detection biases for the rate of initiation of contraceptive implant, which was the primary outcome of this review, because blinding is unlikely to affect this outcome measure. However, as knowledge of group assignment may affect self-report of side effects, we therefore considered this to indicate high risk of bias for an assessment of treatment-related side effects.

Incomplete outcome data

Two included studies had rates of incomplete outcome data of less than 20% (Phemister 1995; Gurtcheff 2011). Thus, we judged both studies as at low risk of attrition bias (Figure 3). Bryant 2016 had a 33% rate of incomplete outcome data, so we determined that this study was at high risk of attrition bias.

Selective reporting

Only two study protocols of the included studies were available for assessing the outcomes of interest (Gurtcheff 2011; Bryant 2016). However, the trial investigators of all included studies reported all relevant outcomes for their objectives, so we judged this domain as at low risk of selection bias.

Other potential sources of bias

In Phemister 1995, the trial investigators excluded nine women after randomisation. The trial investigators of all included studies did not state the definitions of abnormal vaginal bleeding patterns applied in their studies, which was the outcome of interest of this review (Phemister 1995; Gurtcheff 2011; Bryant 2016). We therefore assessed this domain as at unclear risk of bias in each of the included studies.

Effects of interventions

See: [Summary of findings for the main comparison Immediate postpartum insertion compared with delayed insertion of contraceptive implant for contraception](#)

See 'Summary of findings' table 1 ([Summary of findings for the main comparison](#)).

PRIMARY OUTCOME

Rate of initiation of contraceptive implant

All included studies reported the rate of initiation of contraceptive implant at the first postpartum check-up visit (four to six weeks postpartum in Phemister 1995 and Bryant 2016 and four to eight weeks postpartum in Gurtcheff 2011). In Phemister 1995, 121 of 125 (96.8%) women assigned to the immediate postpartum insertion of contraceptive implant received contraceptive implant insertion as per the study protocol, while only 86 of 120 (71.7%) women assigned to the delayed postpartum insertion received implant insertion between four to six weeks postpartum at the time of the scheduled postpartum follow-up visit. These findings were in line with that noted in Gurtcheff 2011, which observed that the rate of initiation of contraceptive implants was remarkably high among women assigned to immediate postpartum insertion when compared to women in the delayed postpartum insertion group (97.1% versus 67.6%, respectively). In Bryant 2016, all 48 women assigned to immediate insertion group received contraceptive implant insertion compared to only 32 of 48 women (67%) allocated to delayed insertion group. There was a higher rate of contraceptive implant initiation among women assigned to immediate insertion group compared with those in the delayed insertion group (risk ratio (RR) 1.41, 95% confidence interval (CI) 1.28 to 1.55; three studies, 410 participants; *moderate quality evidence*; [Analysis 1.1](#); [Figure 4](#); [Summary of findings for the main comparison](#)).

Figure 4. Forest plot of comparison: 1 Immediate versus delayed postpartum insertion of contraceptive implants, outcome: 1.1 Rate of initiation of contraceptive implants.

SECONDARY OUTCOMES

Continuation rate

Continuation rate at six months after delivery

Gurtcheff 2011 and Bryant 2016 reported the continuation rate of contraceptive implant used at six months. The six-month

continuation rate of contraceptive implant use in Gurtcheff 2011 was 97.1% for women allocated to the immediate postpartum insertion, which was comparable to the rate of 95.7% reported for women in the delayed postpartum insertion group. In Bryant 2016, the continuation rate among women who received an immediate insertion was similar to that in women assigned to delayed

insertion group (88% versus 86%, respectively). The meta-analysis using fixed-effects model suggested little or no difference between the groups in the rate of continuation of contraceptive implant use

at six months following delivery (RR 1.02, 95% CI 0.93 to 1.11; two studies, 125 participants; *low quality evidence*; [Analysis 1.2](#); [Figure 5](#); [Summary of findings for the main comparison](#)).

Figure 5. Forest plot of comparison: 1 Immediate versus delayed postpartum insertion of contraceptive implants, outcome: 1.2 Continuation rate.

Continuation rate at 12 months after delivery

Only [Bryant 2016](#) reported the continuation rate of contraceptive implant use at 12 months after delivery. The 12-month continuation rate of contraceptive implant use among women receiving immediate insertion was 81.1%, and it was 77.8% in women receiving delayed insertion. It was unclear whether there was any difference between the groups (RR 1.04; 95% CI 0.81 to 1.34; one study, 64 participants; *very low quality evidence*; [Analysis 1.2](#); [Figure 5](#); [Summary of findings for the main comparison](#)).

Continuation rate at 24 months after delivery

No studies reported this outcome.

Side effects

Mean days of abnormal vaginal bleeding within six weeks postpartum

One included study reported the duration of abnormal vaginal bleeding ([Phemister 1995](#)). Duration of vaginal bleeding among

women in the immediate insertion group was longer than that noted among women receiving delayed insertion of contraceptive implant (mean difference (MD) 5.80 days, 95% CI 3.79 to 7.81; one study, 215 participants; *low quality evidence*; [Analysis 1.3](#); [Summary of findings for the main comparison](#)). However, this difference might not constitute a clinically important benefit as there was no distinction of follow-up haemoglobin level between these two comparison groups ([Phemister 1995](#)).

Heavy, irregular vaginal bleeding or associated severe cramping within 12 months

[Bryant 2016](#) the rate of heavy, irregular bleeding, or associated cramping evaluated at 12 months among women receiving immediate insertion compared to women receiving delayed insertion of contraceptive implant. It was unclear whether there was any difference between the groups (RR 1.01, 95% CI 0.72 to 1.44; one study, 64 participants; *very low quality evidence*; [Analysis 1.4](#); [Figure 6](#)).

Figure 6. Forest plot of comparison: 1 Immediate versus delayed postpartum insertion of contraceptive implants, outcome: 1.4 Other side effects.

Other side effects

Phemister 1995 reported that women in the immediate insertion group experienced a significantly higher rate of adverse effects other than vaginal bleeding including nausea, hair loss, hirsutism, headache, and acne than reported among women receiving delayed insertion (RR 2.06; 95% CI 1.38 to 3.06; one study, 215 participants; *low quality evidence*; Analysis 1.4; Figure 6; Summary of findings for the main comparison).

Participant satisfaction

In Bryant 2016, the trial investigators asked their participants to rate the satisfaction score from zero to 10 during the one year follow-up. There was little or no difference between the groups in participant satisfaction score (MD -0.40, 95% CI -1.26 to 0.46; one study, 64 participants; *low quality evidence*; Analysis 4.1; Summary of findings for the main comparison).

Unintended pregnancy rates

Unintended pregnancy rates at 12 months after delivery

Bryant 2016 reported that the rates of unintended pregnancy occurring within one year after delivery were 13.5% and 7.0% among participants allocated to immediate insertion and those who were assigned to delayed insertion group, respectively. It was unclear whether there was any difference between the groups (RR 1.82, 95% CI 0.38 to 8.71; one study, 64 participants; *low quality evidence*; Analysis 1.6; Summary of findings for the main comparison).

Unintended pregnancy rates at 24 months after delivery.

No studies reported this outcome.

Rapid repeat pregnancy (defined as pregnancy onset within two years of the previous pregnancy)

No studies reported this outcome.

Breastfeeding at six months postpartum

Gurtcheff 2011 and Bryant 2016 reported breastfeeding rate at six months. Gurtcheff 2011 presented Kaplan-Meier curves to evaluate the impact of immediate postpartum insertion of contraceptive implant on exclusive or any breastfeeding compared to that of the delayed postpartum insertion. The rates between the two groups were not significantly different at any time periods. However, numerical data regarding this outcome were insufficient to determine the relative effect at each time point. Attempts to obtain additional data from the investigators were unsuccessful since the trial authors did not reply our requests.

Bryant 2016 reported rates of breastfeeding at six months after delivery among women receiving immediate contraceptive implant insertion compared to women allocated to delayed insertion, which were 30.0% versus 15.0%, respectively. It was unclear whether there was any difference between the groups (RR 2.01, 95% CI 0.72 to 5.63; one study, 64 participants; *low quality evidence*; Analysis 1.7; Summary of findings for the main comparison).

DISCUSSION

Summary of main results

Only three randomised controlled trials (RCTs) met the inclusion criteria of this review. We considered the overall review evidence to be at low risk of bias. Evidence from this review demonstrates that immediate postpartum contraceptive implant insertion significantly increases the rate of postpartum contraceptive implant initiation at the first postpartum check-up visit. The continuation rate of contraceptive implant use at six months

between the two groups was comparable. The mean duration of vaginal bleeding among women receiving immediate insertion of contraceptive implant was longer than that noted among women receiving delayed insertion; however, this difference might not constitute a clinically important benefit as there was no distinction of follow-up haemoglobin level between these two comparison groups. Additionally, rates of abnormal vaginal bleeding between the two comparison groups were comparable regardless of the severity of bleeding. According to the inability to blind the intervention assigned, the difference in the rate of self-reported side effects between the immediate and delayed postpartum insertion of contraceptive implant remains inconclusive. Based on the limited data available from a small single study, there were no significant differences between the two groups in terms of participant satisfaction, unintended pregnancy rate at 12 months, and rate of breastfeeding at six months postpartum.

Overall completeness and applicability of evidence

This review included three RCTs that evaluated immediate versus delayed postpartum insertion of contraceptive implant for contraception in 410 participants in the USA. The study participants were black and Hispanic white young-adult women. Additionally, the study settings were large hospitals in the USA. None of the included studies were conducted in low- or middle-income countries, which often have low postpartum contraceptive prevalence (UN 2013). Thus generalization of these findings to other population or settings should be applied with caution.

All included studies reported the initiation rate of contraceptive implant at the first postpartum check-up visit, which was the primary objective of this review. However, only two included studies reported the continuation rate at six months after delivery and adverse effects. Gurtcheff 2011 and Bryant 2016 reported data regarding the impact of the insertion type of contraceptive implant on breastfeeding at six months postpartum. However, we could not determine its relative effect from the only included study that reported this outcome because it lacked data regarding the actual number of participants in each comparison group (Gurtcheff 2011). Data regarding long-term continuation rate, rate of unintended pregnancy or repeat pregnancy, and participant satisfaction were limited as a single included study reported these data.

Quality of the evidence

Although there was an inability to blind the type of intervention received, it was unlikely to affect the rate of initiation of contraceptive implant and continuation rate. However, knowledge of the intervention assigned may affect self-reporting of treatment-related side effects, thus indicating a high risk of performance and assessment bias for this outcome measures. This compromises the internal validity of an included study when determining the subjective outcomes, such as side effects and participant satisfaction, since an assessment of these events was based on the outcomes retrieved from participants' self-reported data. The higher risk of side effects among women who received an immediate postpartum contraceptive implant insertion versus those who received a delayed insertion should be cautiously viewed; it is unknown whether this is because of knowledge of which intervention had been administered, or the type of contraceptive implant insertion itself, affects outcomes. We extracted data regarding the rates of continuation and unintended

pregnancy, participant satisfaction, and rate of breastfeeding at six months from a small single study that had a high default rate.

We determined the quality of evidence using the GRADE approach for each outcome (see [Summary of findings for the main comparison](#)). We downgraded the quality of the evidence to moderate quality for rate of initiation of contraceptive implants. We downgraded the evidence to low or very low quality for the continuation rate of contraceptive implant, duration of abnormal vaginal bleeding, adverse effects other than vaginal bleeding, participant satisfaction, and rates of unintended pregnancy and breastfeeding at six months (see [Summary of findings for the main comparison](#)).

Thus the quality of the evidence ranged from moderate to very low. The main limitations were imprecision and risk of bias (related to lack of blinding and to attrition).

Potential biases in the review process

With assistance from the Information Specialist, Cochrane Fertility Regulation Group, we made every attempt to include all potential studies including a thorough search of the standard databases, grey literature, conference proceedings, and ongoing trials. However, since only three studies met the inclusion criteria, we cannot exclude the possibility of publication bias.

None of the review authors have any links to drug companies or a financial interest in the prescription of the drugs under assessment, nor were they involved in the conduct of the included studies. Thus, there were no issues related to bias secondary to conflicts of interests in this review.

Agreements and disagreements with other studies or reviews

To date there are no systematic reviews that have compared immediate versus delayed postpartum contraceptive implant insertion. A Cochrane review that assessed the effectiveness of immediate postplacental (within 10 minutes of placenta delivery) insertion of intrauterine device (IUD) for contraception compared to early postpartum insertion (10 minutes to 48 hours) and standard insertion (during the postpartum visit) demonstrated that there was no significant difference in the rates of IUD use among women who received an immediate insertion compared to those who received an early postpartum insertion (odds ratio (OR) 0.46, 95% confidence interval (CI) 0.04 to 5.75) (Lopez 2015). However, IUD use at six months was more likely with immediate insertion of IUD than with standard insertion (OR 2.04, 95% CI 1.01 to 4.09) (Lopez 2015). In this review, the meta-analysis of both included studies revealed the significant higher rate of postpartum contraceptive implant initiation among women assigned to receive immediate insertion compared with women receiving delayed insertion (risk ratio (RR) 1.41, 95% CI 1.28 to 1.55; three studies, 410 participants). These findings therefore indicate that immediate postpartum provision of long-acting reversible contraceptive method can increase the uptake rate of postpartum contraception. Regarding pregnancy rate, Lopez 2015 reported no difference between immediate postplacental and standard insertion, which is consistent with the results of this review.

The inability to blind the intervention assigned in the included studies in this review precludes a reliable assessment of the difference in the rate of self-reported side effects between the

immediate and delayed postpartum insertion of contraceptive implant. A two-year observational study conducted in the USA with 414 women showed no difference in removal rate secondary to abnormal vaginal bleeding among women who received immediate and delayed postpartum insertion of contraceptive implant (19.3% versus 18.4%, respectively) (Ireland 2014). In the prospective cohort from Thailand that evaluated the safety of immediate postpartum insertion of contraceptive implant among 88 asymptomatic HIV type 1-positive women, 62.5% of participants reported to have irregular bleeding at six months, which appeared to be comparable to women who received a standard insertion (Taneepanichkul 2001). In this Cochrane review, although duration of vaginal bleeding among women in the immediate insertion was statistically significant longer than that noted among women who received delayed insertion of contraceptive implant (mean difference (MD) 5.80 days; 95% CI 3.79 to 7.81; one study, 215 participants), this difference might not reach a clinically important level since as there was no distinction of follow-up haemoglobin level between these two comparison groups.

AUTHORS' CONCLUSIONS

Implications for practice

Evidence from this review indicates that the rate of contraceptive implant initiation rate was higher for women randomised to receive implants during the delivery hospitalizations compared with those randomised to receive implants at four to six weeks postpartum. This practice is a very appealing choice in areas with high default rate from postpartum follow-up appointment. Due to a high risk of performance bias and unclear risk of detection bias, the different profiles of the self-reported side effects between the immediate

and delayed postpartum insertion of contraceptive implant remain inconclusive. The unintended pregnancy rate must be interpreted with caution due to the high risk of attrition bias.

Implications for research

The ultimate goal for provision of contraceptive methods is to prevent undesired pregnancy. However, questions remain about whether immediate postpartum insertion of contraceptive implants is more effective than insertion at four to six weeks postpartum in preventing unintended pregnancy and pregnancy-related morbidity and mortality. The available evidence obtained from three included studies in this review only indicates that this intervention could improve the rate of contraceptive implant initiation at the first postpartum follow visit. Further large-scale RCTs with long follow-up periods for determining the rates of long-term contraceptive implant use, unintended pregnancy, and rapid pregnancy after immediate postpartum insertion of contraceptive implant are required. In addition, the uncertainty about whether immediate postpartum contraceptive implant insertion increases the risk of adverse effects than with standard insertion also warrants further study.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bryant 2016

Methods	A randomised controlled trial (RCT) conducted in large hospital in North Carolina, USA Study duration: August 2012 to April 2014 Sample size: 96 participants were recruited to detect 30% difference in contraceptive implant use at 1 year postpartum among peripartum women assigned to receive immediate postpartum insertion (prior to hospital discharge) and delayed postpartum insertion (4 to 6 weeks) of etonogestrel contraceptive implant with a study power of 80% and alpha of 0.05
Participants	Adolescents and young women aged 14 to 24 years, gave birth to a healthy infant, spoke English or Spanish, and desired to use the contraceptive implant. Exclusion criteria included one or more of the following. <ul style="list-style-type: none"> • Current or past history of thrombosis or thromboembolic disorders. • Hepatic tumours. • Active liver disease. • Undiagnosed abnormal genital bleeding. • Known, suspected or history of carcinoma of the breast. • Hypersensitivity to the implant. • Use of hepatic enzyme inducers. • Maternal hospital intensive care unit (ICU) admission after delivery. • Postpartum haemorrhage requiring blood transfusion. • Hospital stay > 7 days postpartum. • Coagulopathy. • Hemolysis, elevated liver enzymes, and low platelet levels (HELLP) syndrome. Most study participants were Hispanic/Latino (40% of women assigned to both immediate and delayed postpartum insertion groups).
Interventions	Intervention arm: participants received etonogestrel contraceptive implant within 48 hours of delivery. Control arm: participants received the same contraceptive method but had been administered at 4 to 6 weeks after delivery.
Outcomes	Primary outcome: contraceptive implant use at 12 months postpartum. Other outcome measures: satisfaction, bleeding patterns, breastfeeding
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned using computer-generated random numbers in blocks of 4 and 6.

Bryant 2016 (Continued)

Allocation concealment (selection bias)	Low risk	The assignments were enclosed in sequentially numbered, opaque, sealed envelopes.
Blinding of participants and personnel (performance bias) primary outcome	Low risk	Although blinding of the participants was not possible, initiation rate was unlikely to be affected by the performance bias.
Blinding of participants and personnel (performance bias) secondary outcomes	High risk	Blinding of the participants was not possible which may affect the self-reported side-effects.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information available.
Incomplete outcome data (attrition bias) All outcomes	High risk	There was a high rate of loss to follow-up in both groups (23% (11/48) and 44% (21/48) in immediate insertion and delayed insertion groups respectively.
Selective reporting (reporting bias)	Low risk	The trial authors reported all potentially relevant outcomes.
Other bias	Unclear risk	Many outcomes in this study were not analysed following an intention-to-treat basis.

Gurtcheff 2011

Methods	<p>A RCT with non-inferiority design conducted in a university hospital in Utah, USA</p> <p>Study duration: January to October 2009</p> <p>Sample size: a total sample size of 34 participants was required in each group when the immediate postpartum insertion of the etonogestrel implant compared to delayed postpartum insertion was expected to delay time to lactogenesis stage II with a non-inferiority margin for the mean difference of 8 hours at the study power of 80% and alpha of 0.05.</p>	
Participants	<p>Healthy peripartum women with healthy, term newborns who desired the etonogestrel implant for contraception.</p> <p>Exclusion criteria were onset of lactogenesis before randomisation, haemorrhage requiring transfusion, severe pregnancy-induced hypertension, prolonged hospitalisation, coagulopathy, liver disease, undiagnosed genital bleeding, or other relative contraindication to etonogestrel implant insertion (known or suspected pregnancy; known, suspected, or history of breast cancer; or hypersensitivity to any of the components in the etonogestrel implant). Women taking inducers of hepatic enzymes were also excluded, including barbiturates, griseofulvin, rifampin, phenylbutazone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, modafinil, protease inhibitors, and herbal products</p> <p>Most study participants were Hispanic white (73% and 60% of women assigned to immediate and delayed postpartum insertion groups, respectively).</p>	
Interventions	<p>Intervention arm: participants received etonogestrel contraceptive implant within 1 to 3 days after delivery.</p> <p>Control arm: participants received delayed insertion of etonogestrel contraceptive implant at 4 to 8 weeks postpartum visit</p>	
Outcomes	<p>Primary outcome: time to lactogenesis stage II documented by maternal perception, lactational failure</p>	

Gurtcheff 2011 (Continued)

Other outcome measures: lactational failure, postpartum contraceptive prevalence, participant-reported vaginal bleeding, and mean creatatocrit value of breast milk at first postpartum visit

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomly assigned using computer-generated random numbers in blocks of varying sizes of 2, 4, and 6.
Allocation concealment (selection bias)	Low risk	Allocation concealment was ensured because the assignments were enclosed in sequentially numbered, opaque, sealed envelopes.
Blinding of participants and personnel (performance bias) primary outcome	Low risk	Although blinding of the participants was not possible, initiation rate was unlikely to be affected by the performance bias.
Blinding of participants and personnel (performance bias) secondary outcomes	High risk	Blinding of the participants was not possible which may affect the self-reported side effects.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information was available.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was a low rate of loss to follow-up in both groups; (17% (6/35) and 17% (6/34) in the immediate insertion and delayed insertion groups respectively.
Selective reporting (reporting bias)	Low risk	The trial authors reported all potentially relevant outcomes.
Other bias	Unclear risk	The trial authors did not provide the definitions of abnormal vaginal bleeding patterns applied in this study, which was an outcome of interest in this review.

Phemister 1995

Methods	<p>A RCT conducted in a large hospital in North Carolina, USA</p> <p>Study duration: June 1992 to February 1993</p> <p>Sample size: 250 participants were recruited to detect 10% difference of prevalence of abnormal vaginal bleeding occurring among peripartum women assigned to receive immediate postpartum insertion (1 to 3 days) and delayed postpartum insertion (4 to 6 weeks) of levonorgestrel contraceptive implant with a study power of 80% and alpha of 0.05</p>
Participants	<p>Peripartum women were offered inclusion in this trial if they intended to use contraceptive implant for contraception, had vaginal births, had predelivery gestational age of 34 weeks or more, had a spontaneous delivery of a grossly intact placenta, had a predelivery haemoglobin value of 8.0 g/dL or higher, and had no contraindications to Norplant insertion as listed by the manufacturer including acute liver disease, acute thromboembolic disorder, abnormal genital bleeding, pregnancy, breast cancer, or an allergy to silicone or levonorgestrel</p> <p>Exclusion criteria included women who intended to breastfeed, experienced postpartum haemorrhage which defined as total estimated blood loss > 500 mL or infection, currently received heparin or war-</p>

Phemister 1995 (Continued)

farin sodium, massively obese (postpartum weight > 250 pounds), or had a history of hypertension, seizures, or bleeding disorders

250 non-breastfeeding postpartum women who met the study inclusion were enrolled. Most women who participated in this study were black (75.2% and 72.5% of women in the immediate and delayed postpartum insertion groups, respectively)

Interventions	Intervention arm: participants received levonorgestrel contraceptive implant within 48 hours of delivery. Control arm: participants received the same contraceptive method but had been administered at 4 to 6 weeks after delivery.
Outcomes	Primary outcome of interest was postpartum bleeding evaluated by the change of haemoglobin level and participants' self-reported of vaginal bleeding patterns Secondary outcomes included blood pressure and weight changes and participants' self-report on other side effects including nausea, hair loss, hirsutism, headaches and acne All outcomes were evaluated during the visit scheduled at 4 to 6 weeks after delivery
Notes	The trial investigators excluded 9 women after randomisation. The included study did not state about the definitions of abnormal vaginal bleeding patterns which were the primary safety concerns of this study

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The allocation sequence was computer generated and sequences was numbered sequentially.
Allocation concealment (selection bias)	Low risk	Allocation concealment was ascertained by enclosing assignments in opaque, sealed envelopes.
Blinding of participants and personnel (performance bias) primary outcome	Low risk	Although blinding of the participants was not possible, initiation rate was unlikely to be affected by the performance bias.
Blinding of participants and personnel (performance bias) secondary outcomes	High risk	Blinding of the participants was not possible which may affect the self-reported side effects.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information was available.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Loss to follow-up rates were 12% and 9% of participants assigned to immediate and delayed insertion groups, respectively.
Selective reporting (reporting bias)	Low risk	The trial authors reported all potentially relevant outcomes.
Other bias	Unclear risk	The trial investigators excluded 9 women after randomisation. In addition, no well-defined terminology of abnormal vaginal bleeding was applied in this trial.

Abbreviations: RCT: randomised controlled trial.

Immediate versus delayed postpartum insertion of contraceptive implant for contraception (Review)

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

Study	Reason for exclusion
Braga 2015	Did not compare immediate versus delayed contraceptive implant insertion.
Brito 2009	Did not compare immediate versus delayed contraceptive implant insertion.
Brito 2012	Did not compare immediate versus delayed contraceptive implant insertion.
Gariepy 2015	Not a RCT.
Ireland 2014	Not a RCT.
Pentickly 2013	Did not compare immediate versus delayed contraceptive implant insertion.
Shabaan 1985	Did not compare immediate versus delayed contraceptive implant insertion.
Taneepanichkul 2001	Not a RCT.
Tocce 2012	Not a RCT.
Wilson 2014	Not a RCT.

Abbreviations: RCT: randomised controlled trial.

DATA AND ANALYSES

Comparison 1. Immediate versus delayed postpartum insertion of contraceptive implants

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Rate of initiation of contraceptive implants	3	410	Risk Ratio (IV, Fixed, 95% CI)	1.41 [1.28, 1.55]
2 Continuation rate	2		Risk Ratio (IV, Fixed, 95% CI)	Subtotals only
2.1 At 6 months postpartum	2	125	Risk Ratio (IV, Fixed, 95% CI)	1.02 [0.93, 1.11]
2.2 At 12 months postpartum	1	64	Risk Ratio (IV, Fixed, 95% CI)	1.04 [0.81, 1.34]
3 Side effect: mean days of abnormal vaginal bleeding	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Mean days of abnormal vaginal bleeding within 6 weeks postpartum	1	215	Mean Difference (IV, Fixed, 95% CI)	5.80 [3.79, 7.81]
4 Other side effects	2		Risk Ratio (IV, Fixed, 95% CI)	Subtotals only
4.1 Heavy, irregular bleeding or associated severe cramping within 12 months	1	64	Risk Ratio (IV, Fixed, 95% CI)	1.01 [0.72, 1.44]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.2 Adverse effects other than abnormal vaginal bleeding	1	215	Risk Ratio (IV, Fixed, 95% CI)	2.06 [1.38, 3.06]
5 Participant's satisfaction	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 At 12 months post partum	1	64	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-1.26, 0.46]
6 Unintended pregnancy rate	1		Risk Ratio (IV, Fixed, 95% CI)	Subtotals only
6.1 At 12 months after delivery	1	64	Risk Ratio (IV, Fixed, 95% CI)	1.82 [0.38, 8.71]
7 Breastfeeding at six months post-partum	1	64	Risk Ratio (IV, Fixed, 95% CI)	2.01 [0.72, 5.63]

Analysis 1.1. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 1 Rate of initiation of contraceptive implants.

Analysis 1.2. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 2 Continuation rate.

Analysis 1.3. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 3 Side effect: mean days of abnormal vaginal bleeding.

Analysis 1.4. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 4 Other side effects.

Analysis 1.5. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 5 Participant's satisfaction.

Analysis 1.6. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 6 Unintended pregnancy rate.

Analysis 1.7. Comparison 1 Immediate versus delayed postpartum insertion of contraceptive implants, Outcome 7 Breastfeeding at six months postpartum.

APPENDICES

Appendix 1. Search strategy

CENTRAL

(postpartum OR post-partum) AND (implant* OR (contracept* AND levonorgestrel) OR norplant OR norplants OR (keto AND desogestrel) OR etonorgestrel OR implanon OR ((subdermal OR subcutaneous) AND implant*) OR (subcutaneous AND implant) OR jadelle)

MEDLINE

(postpartum OR puerperium OR postcesarean OR delivery OR cesarean section) AND ((contracept* AND implant*) OR levonorgestrel OR norplant* OR (keto AND desogestrel) OR etonorgestrel OR implanon OR (subdermal AND implant) OR (subcutaneous AND implant) OR jadelle) AND insert*

Embase

(postpartum OR puerperium OR postcesarean OR delivery OR cesarean section) AND ((contracept* AND implant*) OR (contraceptive devices, female AND implant) OR (contracept* AND (levonorgestrel OR norplant* OR (keto AND desogestrel) OR etonorgestrel OR implanon OR (subdermal AND implant) OR (subcutaneous AND implant) OR jadelle))) AND (insert OR inserting OR inserted OR insertion)

POPLINE

("contraceptive implants" OR levonorgestrel OR norplant OR norplants OR "keto desogestrel" OR etonorgestrel OR implanon OR jadelle OR "subdermal implant" OR "subdermal implants") AND insertion AND (postpartum OR puerperium OR postcesarean OR "post cesarean")

CONTRIBUTIONS OF AUTHORS

Jen Sothornwit initiated the review topic. Jen Sothornwit, Yuthapong Werawatakul, Srinaree Kaewrudee, Malinee Laopaiboon and Pisake Lumbiganon drafted the review. All authors reviewed and approved the final version of the review.

DECLARATIONS OF INTEREST

Jen Sothornwit: none known

Yuthapong Werawatakul: none known

Srinaree Kaewrudee: none known

Pisake Lumbiganon: none known

Malinee Laopaiboon: none known

SOURCES OF SUPPORT

Internal sources

- Department of Obstetrics and Gynecology, Faculty of Medicine, Khon Kaen University, Thailand.
- Department of Epidemiology and Biostatistics, Faculty of Public Health, Khon Kaen University, Thailand.

External sources

- Thailand Research Fund (Distinguished Professor Awards), Thailand.
- Cochrane Thailand, Thailand.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Primary review outcome

In our protocol the primary outcome was 'Postpartum contraceptive prevalence at the first postpartum check-up visit'. This has been re-worded as 'Rate of contraceptive implant initiation at the first postpartum check-up visit'.

Unit of analysis issues

We intended to include studies where individual postpartum women were randomised and cluster-randomized studies where, for example, the hospital was the unit of randomisation. However, we did not find any related cluster-randomised study. In future updates of this review, for studies that use a cluster-randomised design but did not have any information related to the design effect, we will estimate the design effect based on a fairly large assumed intra-cluster correlation of 0.10. We will base this assumption by analogy on studies about implementation research ([Ukoumunne 1999](#); [Campbell 2000](#)).

Assessment of reporting biases

As only three RCTs met the inclusion criteria, we were unable to construct funnel plots to determine the possibility of publication bias as previously stated in the protocol ([Sothornwit 2015](#)). In future updates of this review, we will construct funnel plots that correspond to the findings of the meta-analysis of the primary outcome that this review needs to address if we identify a sufficient number of included studies (i.e. more than 10). We will also perform sensitivity analyses to investigate the effect on the pooled results of the funnel plots ([Sterne 2011](#)).

Subgroup analysis and investigation of heterogeneity

We did not perform subgroup analyses, as we stated in the Cochrane protocol, due to the limited number of included studies. All included studies were conducted in the USA. In future versions of this review, we will perform subgroup analysis to investigate heterogeneity, if feasible, and we will employ the following methods for subgroup analysis.

- We will consider whether an overall summary is meaningful, and if it is, use a random-effects analysis to produce it.
- We plan to perform subgroup analyses according to age of participants (teenagers versus non-teenagers) and population differences (high-income versus low- and middle-income countries).
- We will assess subgroup differences by interaction tests available within RevMan 5 ([RevMan 2014](#)). We will report the results of subgroup analyses quoting the χ^2 statistic and P value, the interaction test, and I^2 statistic value.

Sensitivity analysis

Only three published RCTs were available for this review, which were at low risk of selection bias. Furthermore, we did not find any unpublished studies. Thus we were unable to perform sensitivity analyses as we stated in the Cochrane protocol ([Sothornwit 2015](#)). In future versions of the review we will perform sensitivity analyses, if feasible, in order to determine the impact of the following factors on effect size.

- Repeating the analysis by excluding unpublished studies (if any).
- Repeating the analysis by excluding trials rated as at 'high' or 'unclear' risk of bias for allocation concealment.

INDEX TERMS

Medical Subject Headings (MeSH)

*Contraceptive Devices, Female [adverse effects] [statistics & numerical data]; *Postpartum Period; Breast Feeding [statistics & numerical data]; Contraception [instrumentation] [*methods]; Patient Satisfaction [statistics & numerical data]; Pregnancy, Unplanned; Randomized Controlled Trials as Topic; Time Factors; Uterine Hemorrhage [epidemiology] [etiology]

MeSH check words

Female; Humans; Pregnancy