The Spinal Cord Outcomes Partnership Endeavor (SCOPE) SCI Clinical Trials Tables

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This issue of *Topics in Spinal Cord Injury Rehabilitation* contains the current SCI clinical trials tables that are produced quarterly by the Spinal Cord Outcomes Partnership Endeavor (<http://scope-sci.org/>). Founded 10 years ago, SCOPE is an academic-scientific-industry partnership dedicated to the promotion of high-quality clinical trial protocols, with the ultimate goal of improving treatments available for persons with SCI. To that purpose, SCOPE sponsors a variety of activities including instructional courses at the ASIA and ISCoS scientific meetings, periodic SCI-related topical workshops, outcomes analyses of existing databases to enhance understanding of SCI recovery, and the web-based dissemination (<http://scope-sci.org/trials/>) of the clinical trials tables presented here. The table listing current SCI trials of drugs, cell-based therapies, and surgical interventions (**Table 1**) was first created in 2012, with the companion table listing rehabilitation and technology trials (**Table 2**) first appearing in 2014. Both tables are created from information available on the National Institutes of Health-sponsored clinical trial registry ClinicalTrials.gov (<https://clinicaltrials.gov/>), which currently lists over 224,000 studies covering all disorders/diseases from study centers in all 50 states and 192 countries. A search of the ClinicalTrials.gov database using the term “Spinal Cord Injury” on September 1, 2016 yielded 840 trials, of which 279 trials were listed as having known status (ie, updated trial information within the

previous 2 years) and as currently recruiting or not yet recruiting participants. Information on these 279 trials was then scrutinized to select studies for inclusion in the SCOPE tables that are testing interventions targeting improvement in neurological impairment or related activities outcomes. The 2 tables list a combined total of 85 trials, with 36 studies on the drugs/cells/surgical table and 49 studies on the rehabilitation/technology table. The tables are updated quarterly to include new studies and remove closed studies (those that are completed, terminated, suspended, active but not recruiting, enrolling only by invitation, etc) as well as studies whose recruiting status information has not been updated within the past 2 years. All existing studies are also reviewed quarterly to enable inclusion of updated information. These tables are intended to be a readily accessible resource for the clinical, scientific, and consumer communities interested in SCI research—specifically those studies of interventions to improve neurological and related functional capacity in persons with SCI. The trial-specific NCT number (“NCT” followed by an 8-digit number) available in the table can be used to access more detailed information on the ClinicalTrials.gov website, either by entering the number in the website’s search engine or in a Google, Bing or other web-based search engine. Updates of these tables will be made available periodically in future issues of *Topics in Spinal Cord Injury Rehabilitation*.

Table 1. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of drug, cell, and surgical interventions to improve neurological and related functional outcomes (revised Sept. 1, 2016)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
AO Spine N. America Research Network, US Reeve Foundation, US Dept. of Defense, Rick Hansen Institute/ NCT01597518	Riluzole 2 x 100 mg by mouth or feeding tube the first 24 hr followed by 2 x 50 mg for the following 13 d after injury vs placebo in acute SCI	18-75 yr age	Acute SCI	Began 8/2013	Phase 2/3	Efficacy/Safety	Multicenter phase 2/3 trial of riluzole vs placebo for improving motor recovery in acute SCI
		C4-C8	SCI ≤12 hr	N. America	RCT	Change in ISNCSCI total motor score from baseline to 6 mo of F/U	
		AIS A, B, C	F/U 6 mo	Multicenter 351 subjects	Double-blind		
Rick Hansen Institute, Univ. of Calgary, Alberta Paraplegia Foundation/ NCT01828203	Twice daily IV minocycline vs placebo for over 7 days; All patients receive decompressive spine surgery and blood pressure management per protocol	≥16 yr age	Acute SCI	Began 6/2013	Phase 3 RCT	Efficacy/Safety	800 mg initial dose tapered 100 mg each dose to 400 mg then continued twice daily x 7 d
		C0-C8	SCI ≤12 hr	Canada		ISNCSCI Motor Score recovery from baseline to examination between 3 mo and 1 yr post injury; ISNCSCI Sensory Scores	
		AIS A, B, C, D	F/U 12 mo	248 subjects			
Ohio State Univ./ NCT02524379	72 hour IV infusion of glyburide (RP-1127) started within 6 hours of SCI	18-70 yr age	Acute SCI	Began 8/2015	Phase n.s.	Adverse events	Single-group early phase safety study of IV glyburide in acute SCI
		C4-C8	SCI ≤6 hr	USA multisite	Single-group	Preliminary efficacy (n.s.)	
		AIS A, B, C	F/U 1 yr	10 subjects	Open-label		
Vertex Pharmaceuticals/ NCT02669849	VX-210 (3 mg or 9 mg dose) in fibrin sealant applied to the dura at the time of spinal decompression/ stabilization surgery within 72 hr of SCI	14-75 yr age	Acute SCI	Began 2/2016	Phase 2/3	ISNCSCI UEMS/Motor Level	RCT to determine whether VX-210 delivered during spinal surgery is effective in neurological recovery and functional capacity in persons with acute SCI
		C4-6 motor level each side	SCI ≥72 hr	150 subjects	RCT	SCIM III	
		AIS A, B	F/U 6 mo		Parallel-group	CUE-T	
					Double-blind	GRASSP	
						AIS	
Kringle Pharma, Inc./ NCT02193334	IT injection of 0.6 mg Hepatocyte Growth Factor (HGF) vs placebo starting at 72 hr post injury, then weekly x5 weeks	18-75 yr age	Acute SCI	Began 6/2014	Phase 1/2	Safety/Efficacy	Study of intrathecal HGF vs placebo given within 72 hr then daily for 5 d
		C4-C8	SCI ≤72 hr	Japan	RCT	Adverse events	
		AIS A, B	F/U 24 wk	48 subjects	Placebo-controlled	ASIA Motor Score change 24 wk	
						Pharmacokinetics	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
Jan Schwab, Elise Kroner Fresenius Foundation, Charite Univ./ NCT 02096913	Dolormin extra (ibuprofen) 2400 mg daily (800 mg 3 times per day) for 4 wks (6 subjects) or 12 wks (6 subjects)	18-65 yr age C4-T4 AIS A, B	Acute SCI 4 d ≤ SCI ≤ 21 d F/U 6 mo	Began 6/2014 Germany 12 subjects	Phase 1 Open-label	Safety/Efficacy Severe gastroduodenal bleed Modified Ashworth Scale Neuropathic Pain Scale ISNCSCI	Safety study of oral ibuprofen for 1 or 3 mo in acute SCI, also measuring ISNCSCI, spasticity, and pain outcomes
Hotchkiss Brain Inst., Univ. of Calgary/ NCT02232165	Medical management of blood pressure to target of mean arterial pressure ≥65 mm Hg vs ≥85 mm Hg for 7 days following SCI	≥1-6 yr age C0-T12 AIS A, B, C No central cord	Acute SCI SCI ≤12 hr F/U 1 yr	Began 3/2012 Calgary, Alberta 100 subjects	Phase 3 RCT Parallel-group Double-blind	ASIA Motor Score change ASIA Sensory Score change AIS improvement SF-36 SCIM, FIM	Non-inferiority study of hypotension avoidance vs induced hypertension
Oregon Health and Science Univ., US Dept. of Defense/ NCT02878850	Pharmacological management of blood pressure (BP) in persons with acute SCI; comparing BP kept in a higher range (85-90 mm Hg) vs BP kept in a normal range (mean arterial pressure [MAP] 65-70 mm Hg) for 7 d	≥18 yr age C0-T8 AIS A, B No central cord No penetrating injury	Acute SCI Time post SCI n.s. F/U 6 mo	Not yet recruit USA, multicenter 152 subjects	Phase n.s. RCT Parallel-group Single-blind	ASIA Motor Score change ASIA Sensory Score change SCIM III Pain scores QoL Satisfaction score Cardiovascular adverse events	Randomized trial of early hemodynamic management of patients following acute SCI, comparing 2 BP target ranges
St. Joseph's Hosp./ NCT02495545	CSF drainage (target IT pressure 10 mm Hg) and elevation of MAP with norepinephrine (goal 100-110 mm Hg) vs elevation/maintenance of MAP alone with norepinephrine (goal 85-90 mm Hg) for 5 d	18-75 yr age C4-C8 AIS A, B, C	Acute SCI SCI ≤24 hr F/U 180 d	Began 10/2015 Arizona, Alabama 60 subjects	Phase 2B Parallel-group RCT Open-label	Change in IT pressure ISNCSCI TMS AIS UEMS, LEMS, sensory scores SCIM Pain	RCT to study the effect of CSF drainage and BP support in acute SCI

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Table 1. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of drug, cell, and surgical interventions to improve neurological and related functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcomes & other outcomes	Comments
Kessler Foundation, NIDRR, Acorda Therapeutics/ NCT01621113	Oral dalfampridine (sustained release 4-aminopyridine) vs placebo for 10 wks in chronic motor incomplete SCI receiving locomotor therapy	18-70 yr age	Chronic SCI	Began 6/2012	Phase 2	Change in 6-min walk test at 10 wks and 22 wks F/U	Test of whether dalfampridine improves walking outcomes in chronic motor incomplete SCI
		C4-T10	SCI >12 mo	New Jersey	RCT		
		AIS C, D	F/U 22 wks	46 subjects	Double-blind		
McMaster Univ./ NCT01904591	Dietary supplementation with 50µ gm selenium and 400 IU Vitamin E daily for 1 yr	>18 yr age	Chronic SCI	Began 10/2013	Phase 1	MRI tractography baseline compared to 1 yr follow-up	Study of dietary supplementation with selenium and Vitamin E in chronic SCI
		SCI >1 yr	SCI >1 yr	Hamilton, ON	Open-label	ISNCSCI	
			F/U 1 yr	10 subjects			
Moleac Pte Ltd./ NCT02537899	NeuroAID (a "natural product" combining several Chinese herbal ingredients) given in oral capsule form for 6 mo combined with standard rehabilitation therapies	18-65 yr age	Acute/Subacute SCI	Began 6/2015	Phase 4	AIS	Open-label study of Chinese herbal supplement plus rehabilitation in acute/ subacute SCI
		AIS A, B	3 d to 4 wk post SCI	Malaysia	Open-label	ISNCSCI Motor/Sensory Scores	
				30 subjects	Case series	SCIM	
			F/U 24 mo			SF-8	
						Adverse events	
Emory Univ., Wings for Life/ NCT02274116	Effect of acute intermittent hypoxia (AIH, breathing air with low oxygen) vs room air (breathing air with normal oxygen) placebo on leg function following SCI	18-77 yr age	Chronic SCI	Began 10/2014	Phase 1/2	Change in overground walking speed and endurance	Repetitive exposure of intermittent hypoxia to enhance walking recovery in persons with chronic SCI
		C4-T12	SCI >12 mo	Atlanta	RCT		
		AIS C, D	F/U 4 mo	20 subjects	Double-blind		
					Placebo-controlled Crossover		

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Table 1. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of drug, cell, and surgical interventions to improve neurological and related functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcomes & other outcomes	Comments
Emory Univ., NICHD/ NCT02323698	Effect of acute intermittent hypoxia (AIH, breathing air with low oxygen) with caffeine or placebo vs room air (breathing air with normal oxygen)	18-77 yr age	Chronic SCI	Began 10/2014	Phase 1/2	Change in overground walking speed and endurance	Study on the effects of caffeine and low oxygen therapy on leg function in human SCI
		C2-T11	SCI >12 mo	Atlanta	RCT		
	sham with caffeine or placebo on leg function following SCI (caffeine substudy)	AIS C, D	F/U 2 wks	20 subjects	Double-blind	Muscle strength	
Emory Univ., US Dept. of Defense/ NCT02632422					Placebo-controlled	Coordination	
					Crossover	Kinematics	
						Force production during walking	
	10 sessions of daily acute intermittent hypoxia (dAIH) vs daily room air (dSHAM); ambulatory subjects in both groups will also receive 60 min of walking practice at a frequency of up to 5 d each week for 2 wks	18-65 yr age	Subacute SCI	Began 10/2015	Phase n.s.	TUG	RCT of daily acute intermittent hypoxia vs sham (room air) in nonambulatory and ambulatory subacute incomplete SCI to determine effect on recovery of walking function
		C4-T11	SCI for 2-4 mo	Atlanta, GA	RCT	6-Minute Walk Test	
Emory Univ., NICHD/ NCT02323945		Some motor function below neuro level	F/U 2 wks	125 subjects	Parallel-group	10-Meter Walk Test	
		AIS B, C, D			Double-blind	Pain, spasticity	
						Hypertension	
						Autonomic dysreflexia incidence	
						Change in overground walking speed and endurance	Study to gain understanding of underlying mechanisms of AIH effect on leg function after SCI
						Muscle strength	
						Coordination	
Emory Univ., NICHD/ NCT02323945					Crossover	Kinematics	
						Force production during walking	
						BDNF, Apolipoprotein E	
						Polymorphisms	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
Univ. of Miami Miami Project/ NCT02354625	Surgical implantation of autologous Schwann cells harvested from the sural nerve of the participant transplanted into the epicenter of the participant's SCI	18-65 yr age	Chronic SCI	Began 1/2015	Phase 1	Safety/Efficacy	Study of the safety of autologous human Schwann cell (ahSC) transplantation in participants with chronic SCI receiving rehabilitation
		SCI C5-T12 (thoracic cohort followed by cervical cohort)	SCI ≥12 mo	Miami	Single-group	Change in ISNCSCI exam from baseline to 12 mo	
		AIS A, B, C	F/U 6 mo	10 subjects	Open-label	MRI imaging of the spinal cord	
		SCI ≤3 cm length				Neuropathic pain measure Others: SCIM, FIM, neurophysiology, autonomic, etc.	
Asterias Biotherapeutics/ NCT02302157	Surgical spinal cord implantation of embryonic stem cell-derived oligodendrocyte progenitor cells (AST-OPC1). Dose escalation with sequential cohorts receiving 2, 10, or 20 million AST-OPC1 at a single time-point 14-30 d after injury.	18-69 yr age	Subacute SCI	Began 3/2015	Phase 1/2a	Safety	Phase 1/2a dose escalation study of AST-OPC1 in subjects with cervical AIS A and B SCI
		C5-C7	14-30 days post SCI	USA, multisite	Open-label	Incidence of AEs	
		AIS A, B	F/U 1 yr	35 subjects		ISNCSCI	
						UEMS	
						Motor level	
Pharmicell Co. Ltd./ NCT01676441	Bone marrow-derived autologous mesenchymal stem cells surgically transplanted intrathecally and directly into spinal cord injury following laminectomy; Implant followed by 4 wks of rehabilitation	16-65 yr age	Chronic SCI	Began 8/2008	Phase 2/3	Efficacy/Safety	Ongoing study of autologous bone marrow-derived stem cells followed by 4 wks of rehabilitation
		Chronic SCI	SCI ≥12 mo	S. Korea	Single-group	ASIA Motor Score	
		Cervical level AIS B	F/U 12 mo after surgery	32 subjects	Open-label	ASIA Sensory Score	
		Stable neuro after 1 mo rehab				EMG, neurophysiology	
						MRI	
						AEs	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
Chaitanya Hosp., Pune (Patient self-funded)/ NCT01833975	Intrathecal transplantation of bone marrow-derived autologous stem cell; 100 million cells/dose; 3 doses over 10 d	18-55 yr age	Time post-SCI n.s.	Began 3/2011	Phase 1/2	Safety/Efficacy	Study the safety and efficacy of bone marrow- derived autologous cells for treatment of SCI
		SCI below C4	F/U 6 mo	India	Single-group	Improvement in Frankel score	
		AIS A-D		50 subjects	Open-label	Improvement in ASIA (ISNCSCI)	
Hospital Sao Rafael/ NCT02152657	Autologous mesenchymal cells (bone marrow) transplanted into the spinal cord via transcutaneous injection (location n.s.)	18-65 yr age	Chronic SCI >6 mo	Began 1/2015	Phase 1/2	MRI	Small pilot trial to study percutaneous spinal cord injection of mesenchymal SC
		SCI below T8	F/U 6 mo	Brazil	Single-group	Sensory/motor examination	
		AIS A		5 subjects	Open-label	LEMS/AIS change	
Hospital Sao Rafael/ NCT02574572	Autologous bone marrow mesenchymal stem cell transplantation in patients with cervical chronic and complete SCI (location n.s.)	18-65 yr age	Chronic SCI ≥12 mo	Began 10/2015	Phase 1	AE assessed by spinal cord MRI	Autologous mesenchymal stem cells transplantation in subjects with cervical chronic complete SCI
		C5-C7	F/U 12 mo	Brazil	Single-group	AIS	
		AIS A		10 subjects	Open-label	Sensory mapping	
						Neuropathic pain	
Hospital Sao Rafael/ NCT02574585	Autologous mesenchymal cells transplantation; Two percutaneous injections (location n.s.) of mesenchymal stem cells, with a 3-mo interval between the injections vs randomly assigned control group without any specific intervention	18-65 yr age	Chronic SCI ≥ 12 mo	Not yet recruit	Phase 2	AE assessed by spinal cord	RCT for the evaluation of autologous mesenchymal stem cell transplantation in thoracolumbar chronic complete SCI
		T1-L2	F/U 12 mo	Brazil	RCT	MRI	
		AIS A		40 subjects	Parallel-group	AIS	
					Open-label	Sensory mapping	
						Neuropathic pain	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
Stem Cells Arabia/ NCT02687672	Transplantation into the spinal cord of autologous bone marrow- vs leukapheresis (from a sample of white blood cells)-derived stem cells	5-50 yr age	Chronic SCI	Began 1/2016	Phase 1/2	ISNCSCI	Comparing transplantation of purified autologous bone marrow- vs leukapheresis-derived stem cells for patients with chronic SCI
		Level/AIS n.s.	SCI ≥6 mo, ≤60 mo	Jordan	RCT	Urine & stool incontinence	
				50 subjects	Parallel-group	QoL	
					Open-label	Independence questionnaire	
BioArctic Neuroscience AB/ NCT02490501	Surgical implantation of SC0806 (a biodegradable device with heparin-activated FGF1 and peripheral nerve implants); Both surgical implant and control groups receive rehabilitation (walking training). Control subjects will be offered SC0806 treatment after completion of their rehabilitation	18-65 yr age	Chronic SCI	Began 6/2015	Phase 1/2	Safety: AEs	Rehabilitation-controlled RCT studying SC0806 (a biodegradable device with heparin-activated FGF1 and nerve implants)
		T2-T11	4-48 mo post SCI	Sweden	Parallel-group	MEP improvement	
		AIS A	F/U 18 mo	27 subjects	RCT		
Sun Yat-Sen Univ., 3rd Affil. Hosp./ NCT02481440	IT administration of up to 1 x 10 ⁶ umbilical cord mesenchymal stem cells per kg, every month for 4 mo	18-60 yr age	Acute-chronic SCI	Began 1/2014	Phase 3	ISNCSCI ASIA score change	IT injection of umbilical cord blood mesenchymal stem cells
		SCI level n.s.	2 wk to 1 yr post-SCI	China	Single-group	EMG	
		AIS A, B, C, D	F/U 24 mo	44 subjects	Open-label	Electroneurophysiology	
						AEs	
Chinese Acad. of Science, Univ. of CAPF, Soochow University/ NCT02510365	Collagen scaffold transplanted into spinal cord after acute SCI	18-65 yr age	Acute SCI	Began 4/2015	Phase 1	AIS	Functional neural regeneration collagen scaffold transplantation in complete acute SCI
		C5-T12	SCI ≤21 d	Soochow and Tianjin, China	Single-group	SSEP, MEP	
		AIS A	F/U 12 mo	10 subjects	Open-label	AEs	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcomes & other outcomes	Comments
Chinese Acad. of Science, Univ. of CAPE/ NCT02688049	Surgical implantation of NeuroRegen scaffold with either 10 ⁷ mesenchymal stem cells or 10 ⁷ neural stem cells into the spinal cord in patients with chronic SCI. All patients have surgical removal of spinal cord scar tissue and have post- operative comprehensive rehabilitation.	18-65 yr age	Chronic SCI	Began 1/2016	Phase 1/2	AIS	Study to assess the efficacy & safety of mesenchymal stem cells or neural stem cells combined with NeuroRegen scaffold transplantation in patients with chronic SCI
		C5-T12	Time after SCI n.s.	Tianjin, China	RCT	SSEP/MEP	
		AIS A	F/U 24 mo	30 subjects	Parallel-group	FIM	
					Double-blind	MRI	
Chinese Acad. of Science, PLA General Hosp./ NCT02688062	NeuroRegen Scaffold™ with bone marrow (BM) mononuclear cell transplantation vs intradural decompression and adhesiolysis in persons with chronic SCI	18-60 yr age	Chronic SCI	Began 1/2016	Phase 1/2	AIS	RCT comparing NeuroRegen scaffold with BM mononuclear cells vs intradural decompression with lysis of adhesions
		Thoracic level	Time after SCI n.s.	Beijing, China	RCT	SSEP/MEP	
		AIS A	F/U 24 mo	22 subjects	Parallel-group	FIM	
					Double-blind	MRI	
						Bladder/Bowel function	
						Safety/Tolerability/AE	
InVivo Therapeutics/ NCT02138110	Surgical implantation of PLGA poly-L-lysine scaffold (Neuro-Spinal Scaffold) into the injured spinal cord in subjects with complete thoracic AIS A SCI	16-70 yr age	Acute SCI	Began 4/2014	Phase 3	AIS	Humanitarian Device Exemption (HDE)
		T2-T12	Able to receive implant ≤96 hr after SCI	16 USA centers	Single-group	Motor scores/Sensory scores	Probable Benefit Study to demonstrate safety and probable benefit in support of future studies
		AIS A		20 subjects	Open-label	SCIM III	and an HDE application with subsequent FDA approval
		Can receive implant within 96 hr of SCI MRI contusion ≥4mm	F/U 6 mo			Bowel/Bladder function	
						Incidence of AE	

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcomes & other outcomes	Comments
Washington Univ., US Dept. of Defense/ NCT01714349	Brachialis branch to anterior interosseous nerve transfer	18–65 yr age Cervical SCI No hand function AIS A, B, C or central cord syndrome SCI > 6 mo	Chronic SCI >6 mo F/U 24 mo	Began 10/2012 St. Louis, MO 20 subjects	Phase n.s. Single-group Open-label	UE strength (Manual Muscle Testing) DASH scale SF-36 Complication rates	Study of peripheral nerve transfer for improving UE strength in patients with tetraplegia/no hand function
Univ. of British Columbia/ NCT01579604	Supinator branch to posterior interosseous nerve transfer	≥18 yr age Cervical SCI 12 mo > SCI > 6 mo ICSH 0–5	Chronic SCI 12 mo > SCI > 6 mo F/U 24 mo	Began 6/2012 Vancouver, BC 10 subjects	Phase 4 RCT Open-label	UE strength (Manual Muscle Testing) Active range of motion DASH scale	Study of peripheral nerve transfer for improving UE strength in patients with tetraplegia
Kunming Tongren Hosp., China SCI Network/ NCT02663310	Surgical decompression/ untethering of the spinal cord, combined with daily intensive weight- bearing rehabilitation compared to daily intensive weight-bearing rehabilitation alone	18–60 yr age T1–T12 AIS A	Chronic SCI SCI ≥12 mo F/U 1 yr	Began 7/2015 Kunming, China 30 subjects	Phase n.s. RCT Parallel-group Single-blind	Kunming Locomotor Scale WISCI SCIM AIS Modified Ashworth AEs, Pain	Surgical decompression/ untethering combined with weight-bearing rehabilitation in chronic SCI subjects
Tokyo Univ./ NCT01485458	Early (<24 hr) vs delayed (>2 wk) decompression surgery for acute cervical SCI in patients with cervical canal stenosis without bony injury	20–79 yr age Cervical below C5 AIS C	Acute/Subacute Admitted within 48 hr of SCI F/U 1 yr	Began 12/2011 Japan 100 subjects	Phase 1/2 RCT Open-label	Safety/Efficacy ISNCSCI motor sensory examination; SCIM; walking ability	Test of whether timing of spinal cord decompression is associated with neurological outcome in SCI without fracture/ dislocation

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Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Treatment timing & follow-up	Enrollment	Phase of study	Primary outcome & other outcomes	Comments
Raboud Univ./ NCT01367405	Surgical decompression vs conservative (nonsurgical) treatment in incomplete SCI without spinal instability	≥18 yr age Incomplete SCI without spinal instability	Acute SCI SCI ≤24 hr F/U 2 yr	Began 10/2013 Netherlands 72 subjects— must speak Dutch	Phase n.s. RCT Parallel-group Open-label	Functional outcome at 2 yr post injury based on Japanese Orthopedic Association assessment; arm and hand function by questionnaire	RCT of acute surgical spinal decompression vs conservative management in patients with incomplete SCI
Nantes Univ. Hosp./ NCT02067320	Randomized assignment to early (within 48 hr) vs delayed (at 15 d) spinal decompression surgery	≥18 yr age C2-T1 AIS A-D	Acute SCI SCI eligible for surgery within 48 hr F/U 2 yr	Not yet enrolling France 72 subjects	Phase n.s. RCT Parallel-group Open-label	ISNCSCI TMS, UEMS, CUE WISCI II SCIM III SF-36 MRI AE/Complications	RCT to compare SCI outcomes of decompressive spine surgery within 48 hr vs surgery performed at 15 d

This table is abstracted from the clinical trial registration website www.clinicaltrials.gov using the search term “Spinal Cord Injury” and is updated periodically. The most recent update occurred September 1, 2016 at which time the www.clinicaltrials.gov search found a total of 870 SCI trials. Of these, the status of 292 trials was known and listed as currently recruiting or not yet recruiting. The table includes 36 SCI trials from the search that: (1) are currently actively recruiting or soon-to-be recruiting subjects; (2) are interventional (testing an intervention/treatment) using drugs, cell therapies, surgery, or hypoxia; and (3) targeted neurological or related functional improvement of the spinal cord as outcome measures.

Interventional clinical trials are routinely registered on www.clinicaltrials.gov based on legal requirements* and because scientific journals may require registration for publication of the trial results. Investigators may choose not to register some early phase trials and those testing behavioral interventions, even though they may be important and scientifically rigorous studies.

*U.S. Public Law 110-85 requires the registration and reporting of results of “certain applicable clinical trials,” i.e., controlled interventional clinical trials that are subject to FDA regulation and that involve a Drug or Biologic (other than Phase I investigations), or Device (other than small feasibility studies); <http://www.fda.gov/oc/ohrt/>.

Terms/Abbreviations

AE = adverse event

AIS = The ASIA (American Spinal Injury Association) Impairment Scale is a component of the ISNCSCI that classifies the degree of motor/sensory sparing below the level of injury. The AIS scale ranges from A (most severe, complete injury with no sparing of sensory/motor function in the sacral segments S4-S5 that innervate the anus/rectum) to E (normal). AIS B describes sensory only sparing; AIS C describes sensory and very weak motor sparing; AIS D describes sensory and stronger but not normal motor sparing.

Ashworth/Modified Ashworth = Scale used to measure spasticity severity.

Central Cord Syndrome/Cervical Central Cord Syndrome = Motor incomplete cervical SCI in which the upper extremities are significantly more impaired than the lower extremities.

CSF = cerebrospinal fluid

CUE-T = Capabilities of Upper Extremity Test

DASH = Disability of Arm, Shoulder, Hand scale is a measure of the upper extremity function.

EMG = The electromyogram refers to a physiological test of muscle and nerve function.

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FIM = The Functional Independence Measure was developed to measure the burden of care in persons who were not independent in activities of daily living, hygiene/self-care, and mobility. The FIM and its subscales have been used as an outcome measure of a research subject's independence in the performance of a variety of specific activities.

Frankel Scale = An older scale for classifying severity of injury that was modified in 1992 to create the AIS.

F/U = follow-up

GRASP = Graded Redefined Assessment of Strength, Sensibility, and Prehension is a clinical measurement of upper limb function for use in person with tetraplegia (quadriplegia).

ICSH = International Classification for Surgery of the Hand in Tetraplegia is a clinical measure of hand function used by surgeons performing reconstructive surgery to improve function in persons with tetraplegia.

ISNCSCI = International Standards for Neurological Classification of Spinal Cord Injury—sometimes referred to as the ASIA (American Spinal Injury Association) standards. This refers to the accepted international standards for performing motor/sensory physical examination of persons with spinal cord injury and the classification scheme for documenting the neurological level and the severity (completeness) of injury.

IT = intrathecal, within the subarachnoid space surrounding the spinal cord—e.g., administration of a drug into the subarachnoid space that contains the cerebrospinal fluid (CSF).

IV = intravenous; administration of a drug by vein.

LEMS = lower extremity motor score

MAP = mean arterial pressure

MEP = Motor evoked potentials: an objective physiological test of motor pathway function in the spinal cord.

MRI = magnetic resonance imaging

NCT number = All trials registered with www.clinicaltrials.gov are assigned a registration number that begins with NCT (e.g., NCT01321333). The number listed for the trials in the table can be used in the search field of www.clinicaltrials.gov to access the webpage describing the trial, the study centers, and contact information in more detail.

n.s. = not specified

Open label = A trial in which there is no attempt to conceal the identity of the intervention from the subjects; i.e., there is no “blinding” or “masking” of the intervention—the subjects know that they are receiving either an “active ingredient” or a placebo.

Phase of study = Clinical trials usually progress in phases from 1 to 4. (Note: trials that are not on the path to FDA/regulatory approval [e.g., trials of surgical techniques or rehabilitation therapies] may not have a phase designation.)

1. Phase 1 trials are usually first-in-human or first-in-disease/condition experiments that are intended to demonstrate feasibility (can it be done), safety (is it reasonably safe), and tolerability (are the side effects tolerable). Phase 1 trials usually do not include a comparison control group and as such, do not provide direct evidence of the interventions efficacy. Phase 1 trials usually enroll a small number of subjects and are commonly done at a single study center but may use a small number of collaborating centers.
2. Phase 2 trials follow successful completion of Phase 1. Phase 2 trials are used to develop information on intervention administration (how to give), dose (how much to give), timing (when and how long to give), effect of the intervention on the body (what does it do, beneficial or harmful). Phase 2 trials commonly utilize multiple study centers, many subjects, and include a randomized control group to provide direct information about efficacy and safety of the intervention. Phase 2 trials enable refinement of how to administer the intervention and how to measure its beneficial effects (what Outcome Measurement to use).
3. Phase 3 trials are conducted using the refined protocols developed from Phase 2 trials. Phase 3 trials are often termed “pivotal” studies because they are sufficiently well-designed and rigorously conducted that their results, if positive, can be used to make the case for regulatory approval (e.g., trials that lead to FDA approval for clinical use). Phase 3 trials almost always enroll large numbers of subjects (in the hundreds or more), use multiple study centers, and randomized control group design (with placebo control and double blinding if feasible). The FDA generally requires two successful confirmatory Phase 3 trials of an intervention for approval.
4. Phase 4 trials are conducted after regulatory (e.g., FDA) approval to gather additional safety and efficacy data.

QoL = quality of life

RCT = Randomized controlled trial: a clinical trial in which subjects are randomly (like flipping a coin) assigned to either receive the active treatment or an alternative (control). Well-designed RCTs minimize the influence of variables other than the intervention that might have an effect on the desired outcome. For this reason, they provide the best evidence of efficacy and safety. The most rigorous RCTs utilize a placebo (inactive) control group and blinding (concealing active vs. control assignment) to minimize bias in the interpretation of study results.

SCIM/SCIM II/SCIM III = The Spinal Cord Independence Measure is a measure of a person's ability to perform certain activities independently; i.e., an outcome measure of a research subject's independence in the performance of a variety of specific activities.

SF-36 = Short Form-36 is a patient-reported survey of health status. The SF-36 is commonly used as a measure of health-related quality of life (QoL).

6-Minute Walk Test = Distance that can be walked in 6 minutes.

SSEP = Somatosensory-evoked potentials: an objective physiological test of sensory pathway function in the posterior columns of the spinal cord.

10-Meter Walk Test = Time required to walk 10 meters.

TMS/UEMS/LEMS = Total Motor Score/Upper Extremity Motor Score/Lower Extremity Motor Score are components of the ISNCSCI that include the ASIA Motor Index Score (the TMS) and the subcomponents of the UEMS and the LEMS which are commonly analyzed and reported separately.

UE = upper extremity

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames post-SCI and follow-up	Enrollment	Study phase and study design	Outcome measures	Comments
Univ. of Ioannina/ NCT02031835	Body weight supported treadmill training (BWSTT) as physical therapy treatment to SCI patients	8-88 yr age SCI level n.s. AIS B,C,D	Time post SCI N/S F/U 6 wks	Began 3/2012 Greece 50 subjects	Phase IV Single-group Single-blind	WISCI ISNCSCI Ashworth Quality of life DXA	Effect of BWSTT on quality of life, walking capability, spasticity, functional abilities, and bone health
Hugo W. Moser Research Institute, Kennedy Krieger, Inc./ NCT02774603	Aquatic locomotor training compared to overground locomotor training in improving ambulatory function and health-related quality of life	18-65 yr age C1-C7 AIS C,D Some ability to walk	Chronic SCI SCI >12 mo F/U 16 wks	Began 6/2015 Baltimore 10 subjects	Phase N/A RCT Parallel-group Single-blind	6-Minute Walk Berg Balance SF-36 SCI QL-23	Comparing efficacy of aquatic vs overground locomotor training
Prasat Neurological Inst., Mahidol Univ./ NCT01432990	Robotic gait training plus conventional PT vs conventional PT alone	18-80 yr age C5-T12 AIS C,D	Subacute timing N/S F/U 4 wks	Not begun Thailand 16 subjects	Phase III RCT Single-blind	Wernig Scale Barthel Index ISNCSCI 10-Meter Walk, 6-Minute Walk	Robotic gait training vs conventional rehabilitation in SCI rehabilitation
North Norway Rehabilitation Center/ NCT00854555	Robotic (Lokomat) locomotor training vs manual-assisted locomotor training to improve walking or standing function in persons with SCI	18-70 yr age SCI level n.s. AIS C,D	Chronic SCI SCI ≥2 yr	Began 8/2008 Oslo & Tromsø, Norway 60 subjects	Phase N/A RCT Single-blind	Recovery of ability to walk/stand Improved ADL function Balance, LE strength Sensation, AIS, QoL	ATLET Study: Robotic (Lokomat) vs manual assisted locomotor training

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up				
Instituto Nacional de Rehabilitación/ NCT02749357	Robotic (Lokomat) locomotor training 5 sessions/wk for 6 wk, comparing training session duration of 60 min vs 30 min	≥16 yr age	Chronic SCI	Not yet recruiting	Phase N/A	Gait Rite system measures	Study comparing effectiveness of 2 Lokomat training session durations
		SCI level n.s	SCI ≥6 mo	Mexico City	RCT	Lokomat measures	
		AIS C,D		10 subjects	Single-blind	SCIM III	
Univ. of Manitoba/ NCT02554058	Device: Novel rehabilitation bike incorporating mechanical stimulators on bike pedals; studying effect on balance, walking, and neurophysiology in iSCI	18-65 yr age	Chronic SCI	Began 5/2015	Phase I	MEP amplitude	Effects of training with a novel rehabilitation bike on the functional recovery and corticospinal plasticity
		AIS C,D	SCI ≥12 mo	Manitoba, Canada	Single-group	H-reflex	
		Can walk 10 m	F/U 10 wks	10 subjects	Open-label	Berg Balance	
						10-Meter Walk, 2-Minute Walk	
						WISCI	
Ohio State Univ./ NCT02498548	Motor control training to evaluate the effect of downhill training at moderate speeds on knee function; Comparing uninjured controls vs locomotor trained iSCI without and with knee joint rehabilitation	18-90 yr age	Chronic SCI	Began 6/2015	Phase 1/2	6-Minute Walk test	Eccentric motor control training to improve human SCI: Knee function during walking
		C1-T10	D/C from rehab at least 6 mo	Columbus, OH	RCT	10-Meter Walk test	
		AIS C,D		32 subjects	Parallel-group	Knee power absorption	
		Able to step overground & on treadmill			Single-blind	Eccentric knee contraction	
						Neuromuscular Recovery Scale	
						Berg Balance	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames post-SCI and follow-up	Enrollment	Study phase and study design	Outcome measures	Comments
Ohio State Univ., Univ. of Notre Dame/ NCT02821845	Motor control training (3 times/wk for 12 wks at slow speeds) to evaluate the effect of downhill training on hip function. Comparing uninjured controls vs locomotor trained iSCI without and with hip joint rehabilitation	18-90 yr age	Chronic SCI	Began 6/2015	Phase I/2	6-Minute Walk test	Eccentric motor control training to improve human SCI: Hip function during walking
		C1-T10	Discharged from outpatient rehab ≥6 mo	Columbus, OH	RCT	10-Meter Walk test	
		AIS C,D		32 subjects	Parallel-group	Frontal hip loading response	
		Can take some steps			Single-blind	Neuromuscular Recovery Scale	
Univ. of Miami, NINDS/ NCT02451683	Study of training with and without some stimulation assessing electrophysiological parameters of time domain and location	18-65 yr age	Chronic SCI	Began 4/2015	Phase N/A	Functional tests of arm/hand function	Study of corticospinal function after SCI
		SCI C8 & above	SCI ≥6 mo	Miami, FL	RCT	Cortical neurophysiology	
		Some grasp and reach ability	F/U 5 mo	300 subjects	Crossover	Upper limb movements scale	
					Open-label		
Univ. of California Irvine/ NCT02473614	Use of Music Glove with sensors attached to fingertips connected to music software (e-g., Guitar Hero) compared to conventional hand exercise program	18-80 yr age	Chronic SCI	Began 3/2015	Phase N/A	Box and Block Test	Music Glove and conventional hand exercises to patients with SCIs
		SCI affecting arm and hand function	SCI ≥6 mo	Irvine, CA	RCT	GRASSP	
			F/U 9 wks	20 subjects	Crossover		
					Single-blind		
Hugo W. Moser Research Institute at Kennedy Krieger, Inc./ NCT01005615	Patterned FES ergometry of arm and shoulder in individuals with SCI; Device: RT300-SLSA vs non-FES upper extremity exercise	18-55 yr age	Chronic	Began 9/2009	Phase I/II	Radiography	Does upper extremity FES promote neurological recovery in patients with cervical SCI?
		12 mo < SCI < 20 yr	12 mo < SCI < 20 yr	Baltimore, MD	RCT	Ashworth	
		C1-C6	F/U 12 mo	30 subjects	Parallel-group	CUE	
		AIS A,B			Crossover	Jebsen-Taylor Hand Function	
		No UE FES 4 wk			Single-blind	Box and Blocks Test	
						ISNCSCI	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/exclusion criteria	post-SCI and follow-up				
Univ. of British Columbia, Rick Hansen Institute/ NCT02799966	MyndMove, a noninvasive medical device that uses short, low energy electrical pulses with surface electrodes to cause muscle contractions that result in UE movement. By assisting movement with MyndMove stimulation, patients may gain volitional ability.	≥18 yr age	Acute-Chronic SCI	Not yet begun	Phase N/A	SCIM	Study of the effectiveness of MyndMove therapy in improving the ability of individuals to volitionally move their arms and hands
		C4-C7	Early SCI 10 d to 6 mo	Multicenter	Non-randomized	GRASSP	
		AIS B,C,D	Late SCI >6 mo	Canada/USA	Parallel-assignment	TRI-HFT	
		SCIM Self-Care score ≤10	F/U 7 wks	40 subjects	Open-label	ARAT	
Case Western Reserve Univ., NINDS/ NCT02329652	Implantation and use of networked neuroprosthesis system (NNS) for arm, hand, and trunk function.	≥17yr age	Chronic	Began 12/2014	Phase N/A	ADL Abilities Test	Implanted device for providing hand function, reach, and trunk function to individuals with cervical SCI
		Motor level C4-8	SCI ≥6 mo	Cleveland	Single-group	Grasp-Release Test	
		AIS A,B,C,D	F/U 3 mo	10 subjects	Open-label		
		Elbow flex ≥2/5					
Toronto Rehabilitation Inst., Rick Hansen Foundation, Ontario Neurotrauma Foundation/ NCT01292811	Functional electrical stimulation (complex motion stimulator) vs conventional occupational therapy	Age >18 yr	Subacute	Began 1/2011	Phase III	FIM	Studying the effects of a complex motion stimulator vs standard OT for improving UE function
		SCI <6 mo	SCI <6 mo	Canada	RCT	GRASSP	
		C4-C7	F/U 6 mo	84 subjects	Parallel-group	Jamar hand dynamometer	
		Unable to grasp			Single-blind	Action Research Arm Test	
						SCIM	
						ReJoyce	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/exclusion criteria	post-SCI and follow-up				
Case Western Reserve Univ., MetroHealth Medical Center, NINDS/ NCT01659541	Implantation of spinal cord expiratory muscle stimulator wire leads to restore cough	18-75 yr age	Chronic SCI	Began 4/2015	Phase N/A	Peak expiratory flow	Determine efficacy of spinal cord stimulation, with wire leads, to produce effective cough in patients with SCI
		SCI C8 or above	AIS A: SCI ≥ 6 mo AIS B, C, D ≥ 12 mo	Cleveland, OH	Single-group	Maximum airway pressure	
		AIS n.s.		16 subjects	Open-label	Caregiver Burden Inventory	
		Expiratory muscles weak	F/U 2 yr			Secretion Management Index	
Univ. of Louisville, UCLA, Reeve Foundation, Kessler Foundation/ NCT02339233	Implantation and use of spinal epidural 16 electrode array for spinal cord electrical stimulation to facilitate standing and stepping in persons with SCI	18-75 yr age	Chronic SCI	Began 1/2010	Phase N/A	Voluntary movement	Spinal epidural electrode array to facilitate standing and stepping after SCI
		SCI above T10	SCI ≥ 1 yr	Louisville	Single-group		
		Unable to stand or step independently	F/U 20 mo	10 subjects	Open-label		
NeuroEnabling Technologies, UCLA-Cal Tech/ NCT01949285	Study of transcutaneous electrical stimulation of the lumbosacral spinal cord to: (1) assess spared function following an SCI; and (2) use this same paradigm for rehabilitation	21-65 yr age	Chronic SCI	Began 6/2015	Phase N/A	ISNCSCI	Prototype transcutaneous stimulation device will be used to assess and rehabilitate spared spinal cord function
		C1-T12 SCI	SCI ≥ 1 yr	Los Angeles	RCT	SCIM	
		AIS A,B,C	F/U 16 wks	24 subjects	Double-blind	Ashworth	
		Not on ventilator or antispasticity Rx			Sham control	EMG	
					Crossover	Kinematic analysis	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up				
NeuroEnabling Technologies, UCLA-Cal Tech/ NCT01906424	Study to determine if transcutaneous electrical stimulation of the spinal cord at 1 or 2 sites combined with training can help improve arm and hand function in people with cervical SCI	18-65 yr age	Chronic SCI	Began 4/2016	Phase N/A	ISNCSCI	Prototype device that delivers transcutaneous electrical stimulation to stimulate the cervical spinal cord
		C1-C7	SCI ≥1 yr	Los Angeles	RCT	CUE	
		AIS C	F/U 12 wks	15 subjects	3 groups	GRASSP	
		Not on ventilator or antispasticity Rx			Crossover	SCIM	
UCLA/ NCT02331979	Transcutaneous electrical and/or magnetic stimulation for spinal cord neuromodulation to improve urinary bladder function in persons with SCI	18-45 yr age	Chronic SCI	Began 9/2015	Phase 0	Urine flow	Study of spinal cord neuromodulation to improve bladder function in subjects with SCI
		C2-T8 SCI	SCI ≥1 yr	Los Angeles	Single-group	Voided volume	
		AIS A,B	F/U 48 mo	24 subjects	Open-label		
						ARAT	
UCLA/ NCT02313194	Study of implanted epidural electrode array for spinal cord stimulation to improved arm and hand function in subjects with nonprogressive SCI above C5	≥18 yr age	Chronic SCI	Began 7/2013	Phase 1/2	Assessment of arm and hand function	Spinal cord stimulation to improve the ability to move in spinal cord injured humans
		SCI above C5	SCI ≥1 yr	Los Angeles			
				12 subjects			
Dept. of Veterans Affairs, NIH/ NCT01923662	Device: IST-16 (16-channel implanted stimulator-telemeter) for standing in persons with paralysis resulting from neurological disorder such as low cervical/thoracic spinal cord injuries (C6-T12)	≥21 yr age	Chronic SCI	Began 4/2013	Phase N/A	Elapsed standing time for different stimulation paradigms	Multiple-contact peripheral nerve cuff electrodes to selectively activate portions of a muscle to improve fatigue characteristics
		C6-T12	SCI ≥6 mo	Cleveland, OH	Single-group		
		AIS n.s.	F/U 12 mo	10 subjects	Open-label	Subject impression of stability	
						Body weight distribution	
						Standing stability measures	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames post-SCI and follow-up	Enrollment	Study phase and study design	Outcome measures	Comments	
Case Western Reserve Univ., NIH, VA Office of R&D/ NCT00623389	Device: IST-16 (16-channel implanted stimulator-telemeter) with pre- and post-surgical training to facilitate exercise, standing, stepping and/or balance in people with various degrees of paralysis	≥18 yr age	Chronic SCI	Began 5/2005	Phase N/A	Standing, walking and balance performance	Evaluation of an advanced lower extremity neuroprostheses	
		C6-T12 or other paralysis	SCI ≥6 mo	Cleveland, OH	Single-group	Standing duration, reachable workspace, and ability to perform other functional ADLs		
		AIS A,B,C	F/U 12 mo	10 subjects	Open-label			
		Normal ROM						
Case Western Reserve Univ., VA Office of R&D/ NCT01474148	Device: IRS-8 (8-channel implanted stimulator-telemeter) to facilitate stability of the trunk and hips; Study of the effect of stabilizing and stiffening the trunk with FES to change the way persons with SCI sit, breathe, reach, push a wheelchair, roll in bed	≥21 yr age	Chronic SCI	Began 7/2011	Phase 1	Effect of trunk stimulation on control seated posture, respiration, seated interface pressures, reach ability, seated stability & personal mobility	Surgical implantation of an 8-channel FES system to facilitate stability of the trunk and hips	
		C4-T12	SCI ≥6 mo	Cleveland, OH	Single-group			
		AIS A,B,C	F/U up to 36 mo	10 subjects	Open-label			
American Society of Thermalism and Climatology/ NCT02333695	Device: Medical device for magnetic therapy. Percutaneous magnetic stimulation of the spinal cord to reverse signs and symptoms of SCI (autonomic dysreflexia, neurogenic bowel & bladder, spasticity, erectile dysfunction, cough impairment)	18-70 yr age	Time post SCI N/S	Began 1/2015	Phase N/A	↓ Hyperreflexia (autonomic dysreflexia)	Study of the effects of spinal magnetic stimulation on autonomic dysreflexia, spasticity, bowel, bladder, and erection function	
		Confirmed central nervous system lesion	F/U 45 d	Newark, NJ	Single-group	Stimulation of erections, bowel movements, bladder emptying		
		SCI level n.s.		50 subjects	Open-label			
		AIS n.s.				Reduced spasticity	Induced cough	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
			post-SCI and follow-up					
Univ. of Zurich/ NCT02165774	Implanted sacral neuromodulation for improvement in lower urinary tract dysfunction (LUTD) such as urgency, frequency, incontinence, retention; Comparison of outcomes with neuromodulation turned on vs off	≥18 yr age	Chronic/stable	Began 4/2012	Phase N/A	“Successful” neuromodulation	Study of bladder function/physiology outcomes with	
		Neurogenic LUTD not responsive to drug therapy	neurologic injury >12 mo	Switzerland	RCT	Neuro-urological assessments	neuromodulation stimulator on vs off	
		Level/AIS n.s.		60 subjects	Double-blind	Neurophysiological assessments		
					Placebo-controlled	Bladder/urethra stim perception thresholds		
Univ. of Miami, NINDS/ NCT02446210	Magstim 200 stimulator for transcranial magnetic stimulation and electrical peripheral nerve stimulation	18-65 yr age	Subacute/Chronic	Began 3/2015	Phase N/A	Motor cortical excitability	Neural control of bilateral hand, arm, and leg movements after SCI	
		Injury above L5	SCI ≥1 mo	Miami, FL	RCT	EEG/EMG		
		Can grip bilaterally	F/U 5 mo	514 subjects	Crossover	Enhanced motor UE		
		Can ambulate a few steps			Open-label	Enhanced motor LE		
Cleveland Clinic/ NCT01539109	Transcranial Direct Current Stimulation (tDCS) vs sham tDCS in incomplete cervical SCI patients undergoing rehabilitation training	18-75 yr age	Chronic SCI	Began 11/2011	Phase N/A	UEMS	Study of tDCS combined with training of UE in incomplete tetraplegia	
		SCI >6 mo	SCI >6 mo	Cleveland	RCT	MRI of brain		
		Cervical level AIS B,C,D	F/U 3 mo	10 subjects	Parallel-group	TMS		
					Double-blind			
McMaster Univ./ NCT02351921	Transcranial magnetic stimulation (tMS) delivered as noninvasive “continuous theta-burst stimulation” to alter motor output to a forearm muscle and touch perception in persons with chronic incomplete SCI	18-60 yr age	Chronic SCI	Not begun	Phase N/A	MEP changes	Repetitive transcranial magnetic stimulation in individuals with SCI	
		C4-T1	SCI >1 yr	Hamilton, Ontario	RCT	Change in forearm muscle force		
		AIS B,C,D	F/U 30 min	20 subjects	Double-blind	Change in touch perception		
					Crossover			

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames post-SCI and follow-up	Enrollment	Study phase and study design	Outcome measures	Comments
Univ. of Sao Paulo General Hospital/ NCT02562001	Active vs placebo high definition transcranial electrical direct-current stimulation (tDCS) followed by robotic Lokomat BWSIT training and ARMEO Spring	18-65 yr age	Subacute/Chronic	Not begun	Phase N/A	WISCI	Study of tDCS on patients receiving gait training (Lokomat) and ARMEO Spring
		SCI level n.s.	1 mo ≤ SCI ≤ 36 mo	Sao Paulo, Brazil	RCT	AIS	
		AIS C,D	F/U 18 wks	20 subjects	Placebo-control	Ashworth	
				Double-blind	Berg Balance		
						10-Meter Walk, 6-Minute Walk	
						SCIM	
Bronx VA Medical Center/ NCT02469675	Transcranial magnetic stimulation; median nerve stimulation; cervical transcutaneous stimulation. Combinations of magnetic and electrical stim will be compared to determine optimal effect on nerve circuits.	21-65 yr age	Chronic SCI	Began 6/2015	Phase N/A	MEP	Paired stimulation to increase cortical transmission to hand muscles: Pilot study
		C2-C8	SCI ≥12 mo	Bronx, NY	RCT	Hand dexterity	
		iSCI with ≥3/5 strength of finger muscles	F/U 90 min	30 subjects	Crossover	Grip strength	
				Single-blind	Neurophysiology		
Oregon Health and Science University, Shepherd Center, NINDS/ NCT01498991	Assisted Movement and Enhanced Sensation (AMES) treatment for SCI leg rehabilitation; Physical assistance of movement and vibratory stimulus to enhance proprioception	18-65 yr age	Chronic	Began 11/2011	Phase I/II	Gait velocity (GAITRite)	Study of AMES device for improving LE sensation and volitional movement
		SCI > 1 yr	SCI > 1 yr	Georgia, Oregon, 10 subjects	Single-group	Vibration threshold	
		All SCI levels	F/U 26 wks		Open-label	Ashworth	
		AIS C,D			10-Meter Walk		
Oregon Health and Science Univ./ NCT01974635	Assisted Movement and Enhanced Sensation (AMES) treatment for improved sensory and motor function of the UE in persons with iSCI or brain injury, stroke	18-65 yr age	Time post SCI N/S	Began 10/2013	Phase I/II	Joint Position Test (proprioception)	25 AMES treatments over 8-13 wks, at a rate of 2-3 sessions per week
		iSCI	F/U 13 wks	Portland, OR	Single-group	Frisbee Test	
		sensorimotor deficit in hand/ wrist		10 subjects	Open-label	Box and Block Test	
					Strength Test		

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Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up				
Shepherd Center, NIH/ NCT02340910	Various frequencies and durations of whole body vibration compared to transcutaneous electrical spinal cord stimulation for improvement in spasticity and walking in persons with motor incomplete chronic SCI	16-65 yr age	Chronic SCI	Began 1/2015	Phase N/A	Spasticity (Pendulum Test)	Dose-response effects of whole body vibration on spasticity and walking in SCI
		T12 or higher	SCI ≥6 mo	Atlanta	Single-group	Walking speed	
		AIS C,D		34 subjects	Open-label		
NCMRR, NICHD, NIDCD, VA Office of R&D/ NCT00912041	Implantation of the BrainGate2 sensor electrode array into the motor cortex; training implanted subjects to control a computer cursor and other assistive devices with their thoughts	18-75 yr age	Time post SCI N/S	Began 5/2009	Phase N/A	Safety	4x4 mm BrainGate2 sensor is placed into the motor cortex, connected to a percutaneous pedestal
		Cervical SCI	F/U 1 yr	4 centers, USA	Single-group	Feasibility of BrainGate2 to establish the parameters for a larger clinical study (appropriate neural decoding algorithms, endpoints, success criteria, etc.)	
		AIS A,B,C,D		15 subjects	Open-label		
		Lives ≤3 hr drive					
California Inst. of Technology, UCLA, Casa Colina/ NCT01958086	Implantation of 2 Neuroport electrode arrays in posterior parietal cortex allowing direct brain-control of a computer interface. Ultimate objective is to allow the patient autonomous control over the Google Android tablet operating system.	22-65 yr age	Time post SCI N/S	Began 10/2013	Phase N/A	Subject control of tablet computer	Feasibility study for use of a brain implant for neural control of a tablet computer
		High cervical SCI	F/U 1 yr	Pomona, CA	Single-group	Absence of infection or irritation	
		Lives <60 miles from study center; not on ventilator		2 subjects	Open-label	Adverse events	
Univ. of Pittsburgh, DARPA, US Dept. of Defense, Johns Hopkins Univ./ NCT01894802	Implantation of microelectrode cortical recording and stimulating (CRS) arrays in the motor cortex and sensory cortex of the brain for neural activity recording and use in control of external devices	22-70 yr age	Chronic condition	Began 12/2013	Phase N/A	Safety: array not removed for safety during 12 month F/U	Two Blackrock microsystems CRS arrays will be implanted in the motor cortex and sensory cortex.
		Limited or no ability to use hands due to cervical SCI or other condition	SCI ≥1 yr	Pittsburgh	Single-group	Efficacy: long-term recording of neural activity and successful control of external devices	
			F/U 12 mo	5 subjects	Open-label		

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames			Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up					
Univ. of Pittsburgh, US Dept. of Defense, Johns Hopkins Univ./ NCT01364480	Implantation of 2 NeuroPort electrode arrays in the motor cortex of the brain to demonstrate the safety and efficacy for long-term recording of brain activity	18-70 yr age	Chronic condition	Began 5/2011	Phase N/A	Safety: array not removed for safety during 12-mo F/U	Two Blackrock microsystems NeuroPort arrays will be implanted in the motor cortex.	
		Limited or no ability to use hands due to cervical SCI or other condition	SCI ≥1 yr	Pittsburgh	Single-group	Efficacy: long-term recording of neural activity and successful control of external devices		
			F/U 12 mo	5 subjects	Open-label			
Univ. of Southern California, Rancho Los Amigos/ NCT01964261	Implantation of 3 Neuroport electrode arrays to enable learned control of an end effector (for reach and grasp tasks) by thought augmented with sensory feedback via intracortical brain stimulation	22-65 yr age	Time after SCI N/A	Began 11/2013	Phase N/A	Patient control of end effector (virtual or physical)	Providing closed loop cortical control of extracorporeal devices to patients with tetraplegia	
		High cervical SCI AIS N/A	F/U 1 yr	California	Single-group	Absence of infection or irritation		
				2 subjects	Open-label			
Aristotle Univ. of Thessaloniki/ NCT02443558	Emotiv EPOC wireless EEG headset use for control of MERCURY v2.0 robotic arms, a noncommercial 6 degree-of-freedom bimanual robotic arms device	≥14 yrs age	Time after SCI N/A	Not begun	Phase N/A	Brain Computer Interface Control	Brainwave control of a wearable robotic arm for rehabilitation and neurophysiological study in cervical spine injury	
		SCI at cervical, thoracic, or lumbar levels	F/U 1 yr	Greece	Non-randomized	SCIM III		
		AIS A,B,C,D,E		30 subjects	Parallel-group			
Univ. of Miami/ NCT02564419	Uninjured controls				Open-label			
		22-50 yr age	Chronic SCI	Began 11/2015	Phase N/A	Neurological exams	Early feasibility study of a Medtronic Activa PC+S system for persons living with SCI	
		C5-6 level	Time post-SCI N/A	Miami, FL	Single-group	Questionnaires		
		AIS A,B		3 subjects	Open-label	Functional hand testing		
						AIS Motor/Sensory scores	SF-36	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up				
The Ohio State Univ., Ali Rezai, MD/ NCT01997125	Neurobridge System utilizing NeuroPort electrode array implant into motor cortex coupled with external neuromuscular stimulator to produce volitional UE movement controlled by EEG activity	21-89 yr age	Chronic	Began 11/2013	Phase N/A	Achievement of voluntary movement of the UE	Neural bridge system implant and external stimulator for reanimation of UE function in tetraplegia
		C4-C6	SCI ≥1 yr	Ohio	Single-group		
		AIS A	F/U 9 mo	5 subjects	Open-label		
Rehabilitation Inst. of Chicago, NIH/ NCT01608438	Comparison of 2 ways of customizing the body-machine interface over 40 sessions (spread over 8 months): (1) SCI static—the body-machine interface is static; (2) SCI Machine Learning—there is a machine learning algorithm that adapts to the movements made by the subject	18-65 yr age	Time post SCI N/S	Began 2/2013	Phase N/A	Time to task completion (data entry and navigation of virtual or real obstacle course)	Subjects drive power wheelchairs, interact with computers through interface that maximizes effectiveness of residual motor function
		C3-C6	F/U 8 mo	Chicago, IL	Non-random		
		AIS A,B,C		46 subjects	Parallel-group		
New York Univ. School of Medicine/ NCT02793635	15 sessions of Indego powered exoskeleton use as a gait training device for subjects with complete or incomplete paraplegia due to SCI				Single-blind	Movement smoothness	
						UE strength	
						State-Trait Anxiety Inventory	
						Functional/Ambulation Category	Study to measure the impact of gait training with the Indego device on walking function after SCI
						10-Meter Walk Test	
						6-Minute Walk Test	
		Some LE function	Chronic SCI	Not yet begun	Phase N/A		
		Height 5'1" -6'3"	SCI ≥1 yr	New York	Open-label		
		Weight ≤250 lbs	F/U 3 wks	25 subjects	Single-group		

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames			Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/ exclusion criteria	post-SCI and follow-up					
Univ. of Alberta/ NCT02322125	Use of ReWalk exoskeleton to train walking in individuals with chronic SCI	18-70 yr age	Chronic SCI	Began 6/2014	Phase 1	6-Minute Walk Test	Characteristics of persons with SCI who most benefit from ReWalk training; feasibility of ReWalk for home/community ambulation	
		Height 5'3" - 6'4"	SCI ≥1 yr	Alberta	Single-group	10-Meter Walk Test		
		Weight ≤180 lbs	F/U 20 wks	15 subjects	Open-label	Manual muscle strength testing		
		Does not walk or walks ≤0.4 m/s				Functional ambulation profile		
		SCI level n.s.				Balance		
James J. Peters VAMC/ NCT02314221	Use of ReWalk and Ekso exoskeletons vs usual activity control group	18-70 yr age	Chronic SCI	Began 2/2015	Phase 3	10-Meter Walk Test	Study of exoskeletal-assisted walking to improve mobility, bowel function and cardio-metabolic profiles in persons with SCI	
		Paraplegia T3 and below (New York); Above T2 (Maryland and New Jersey)	SCI ≥6 mo	New York, New Jersey, Maryland	RCT	6-Minute Walk Test		
			F/U 3 mo	64 subjects	Crossover	Timed Up and Go		
					Open-label	Advanced walking skills		
						Bowel function		
Total body fat mass (DXA)								
(Continue)								

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Inclusion/ exclusion criteria	Time frames post-SCI and follow-up	Enrollment	Study phase and study design	Outcome measures	Comments
Rex Bionics/ NCT02417532	Study of user abilities in REX device	10-90 yr age	Time post SCI N/S	Began 5/2015	Phase N/A	Defined REX activity completion	Safety and feasibility evaluation of robot assisted physiotherapy exercises with REX
		C4-L5		Australia, New Zealand, UK	Single-group	Transfer to REX	
		Body dimension criteria (device fit)		100 subjects	Open-label	Autonomous REX control	
						Patient Satisfaction	
Rehabilitation Inst. of Chicago, Otto Bock Healthcare Products/ NCT02089880	Comparison of microprocessor-controlled knee-ankle-foot orthosis (C-Brace) vs stance-control knee-ankle-foot orthosis (SCO) to improve functional outcomes in individuals with lower extremity impairment	18-80 yr age	Time post SCI N/S	Began 2/2014	Phase 2	6-Minute Walk	Comparing functional outcomes in individuals using microprocessor-controlled orthosis versus stance-control orthosis
		LE functional impairment due to neurologic condition	F/U 16 wks	Chicago, IL	RCT	10-Meter Walk	
				24 subjects	Crossover	LE muscle strength	
		Prior active use of SCO or KAFO			Open-label	Berg Balance	
						Functional gait assessment	
						Stair/hill assessment indices	
Hugo W. Moser Research Institute at Kennedy Krieger, Inc./ NCT01491789	Single group study of the benefits of the VSail-Access simulator (virtual sailing simulator)	18-55 yr age	Chronic	Began 5/2011	Phase I/II	ISNCSCI	Studying the benefits of a recreational and therapeutic program for people with SCI using the VSail-Access sailing simulator
		SCI >6 mo	SCI >6 mo	Baltimore, MD	Single-group	SCI-QL-23	
		SCI C1-S1	F/U 12 wks	20 subjects	Open-label	Functional reach	
		ALS A,B,C,D				Grasp/pinch	
						Sailing Ability Questionnaire	

(Continue)

Table 2. Spinal Cord Outcomes Partnership Endeavor (SCOPE, www.scope-sci.org) current SCI clinical trials of rehabilitation and technological interventions to improve functional outcomes (revised Sept. 1, 2016) (CONT.)

Sponsor/NCT	Intervention	Time frames		Enrollment	Study phase and study design	Outcome measures	Comments
		Inclusion/exclusion criteria	post-SCI and follow-up				
Univ. of Zurich/ NCT02149186	Interactive Computer-based Therapy System for Legs (iCTuS-L)—a virtual reality (VR)-based observation, motor imagery, and execution to treat lower limb neuropathic pain and motor dysfunction	16-80 yr age	Acute or chronic acute <3 mo	Began 10/2009	Phase N/A	Questionnaires: Neuropathic pain, depression, ADL, walking aids, personal assistance, gait	Interactive motor imagery in virtual reality
		SCI level n.s.	Chronic >1 yr	Zurich, Switzerland	Single-group		
		AIS C,D	F/U 16 wks	72 subjects	Open-label		
		Has neuropathic pain and/or motor deficits				Transcranial magnetic stimulation	
						Transcutaneous PN stimulation	

This table is abstracted from the clinical trial registration website www.clinicaltrials.gov using the search term "Spinal Cord Injury" and is updated periodically. This table was derived from a www.clinicaltrials.gov search on June 2, 2016 that found a total of 840 SCI trials. Of these, 279 trials were listed having known status and as currently recruiting or not yet recruiting. The table includes 50 SCI trials from the search that: 1) are currently actively recruiting or soon-to-be recruiting subjects; 2) are interventional (testing an intervention/treatment) using rehabilitation, neural stimulation and/or assistive technology strategies and 3) targeted improvement in neurological impairment or related activities outcomes.

Interventional clinical trials are routinely registered on www.clinicaltrials.gov based on legal requirements* and because scientific journals may require registration for publication of the trial results. Investigators may choose not to register some early phase trials and those testing behavioral interventions, even though they may be important and scientifically rigorous studies.

*U.S. Public Law 110-85 requires the registration and reporting of results of "certain applicable clinical trials," i.e., controlled interventional clinical trials that are subject to FDA regulation and that involve a Drug or Biologic (other than Phase I investigations), or Device (other than small feasibility studies); <http://prinfo.clinicaltrials.gov/fdaaa.html>.

Terms/Abbreviations

ADL = activity of daily living

AIS = ASIA (American Spinal Injury Association) Impairment Scale is a component of the ISNCSCI that classifies the degree of motor/sensory sparing below the level of injury. The AIS scale ranges from A (most severe, complete injury with no sparing of sensory/motor function in the sacral segments S4-S5 that innervate the anus/rectum) to E (normal). AIS B describes sensory only sparing. AIS C describes sensory and very weak motor sparing; AIS D describes sensory and stronger but not normal motor sparing.

ARAT = Action Research Arm Test is a clinical measurement of upper limb function.

Ashworth = Ordinal measurement scale used to rate the severity of spasticity.

Barthel Index = Ordinal scale used to measure performance in activities of daily living (ADL).

Berg Balance Scale = A 14-item objective measure designed to assess static balance and fall risk.

CUE = Capabilities of Upper Extremity is a clinical measurement of upper limb function for use in person with tetraplegia (quadriplegia).

D/C = discharge

DXA = Dual-energy X-ray absorptiometry is a test that measures bone mineral density.

EMG = The electromyogram refers to a physiological test of muscle and nerve function.

F/U = follow-up

FES = functional electrical stimulation

GRASP = Graded Redefined Assessment of Strength, Sensibility, and Prehension is a clinical measurement of upper limb function for use in person with tetraplegia (quadriplegia).

H-reflex = Electrophysiological measure that assesses the monosynaptic reflex; used as a measure of reflex pathway continuity and excitability.

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- iSCI = incomplete spinal cord injury
- ISNCSCI = International Standards for Neurological Classification of Spinal Cord Injury—sometimes referred to as the ASIA (American Spinal Injury Association) standards. This refers to the accepted international standards for performing motor/sensory physical examination of persons with spinal cord injury and the classification scheme for documenting the neurological level and the severity (completeness) of injury.
- LE = lower extremity
- MEP = Motor-evoked potentials; an objective physiological test of motor pathway function in the spinal cord.
- N/A = not applicable
- N/S = not specified
- n.s. = not specified
- NCT number = All trials registered with www.clinicaltrials.gov are assigned a registration number that begins with NCT (e.g., NCT01321333). The number listed for the trials in the table can be used in the search field to access the webpage describing the trial, the study centers, and contact information in more detail.
- Open label = A trial in which there is no attempt to conceal the identity of the intervention from the subjects; i.e., there is no “blinding” or “masking” of the intervention—the subjects know that they are receiving the “active ingredient” rather than a placebo.
- Phase of study = Clinical trials usually progress in phases from 1 to 4. Note: Trials of rehabilitation and technology interventions are commonly not classified by Phase of Study; i.e., not applicable (N/A) or not specified (N/S)—sometimes documented by investigators as Phase 0
1. Phase 1 trials are usually first-in-human or first-in-disease/condition experiments that are intended to demonstrate feasibility (can it be done), safety (is it reasonably safe), and tolerability (are the side effects tolerable). Phase 1 trials usually do not include a comparison control group and as such, do not provide direct evidence of the interventions efficacy. Phase 1 trials usually enroll a small number of subjects and are commonly done at a single study center but may use a small number of collaborating centers.
 2. Phase 2 trials follow successful completion of Phase 1. Phase 2 trials are used to develop information on intervention administration (how to give), dose (how much to give), timing (when and how long to give), effect of the intervention on the body (what does it do, beneficial or harmful). Phase 2 trials commonly utilize multiple study centers, many subjects, and include a randomized control group to provide direct information about efficacy and safety of the intervention. Phase 2 trials enable refinement of how to administer the intervention and how to measure its beneficial effects (what Outcome Measurement to use).
 3. Phase 3 trials are conducted using the refined protocols developed from Phase 2 trials. Phase 3 trials are often termed “pivotal” studies because they are sufficiently well-designed and rigorously conducted that their results, if positive, can be used to make the case for regulatory approval (e.g., trials that lead to FDA approval for clinical use). Phase 3 trials almost always enroll large numbers of subjects (in the hundreds or more), use multiple study centers, and randomized control group design (with placebo control and double blinding if feasible). The FDA generally requires two successful confirmatory Phase 3 trials of an intervention for approval.
 4. Phase 4 trials are conducted after regulatory (e.g., FDA) approval to gather additional safety and efficacy data.
- PT = physical therapy
- QoL = quality of life
- RCT = Randomized Controlled Trial: a clinical trial in which subjects are randomly (like flipping a coin) assigned to either receive the active treatment or an alternative (control). Well-designed RCTs minimize the influence of variables other than the intervention that might have an effect on the desired outcome. For this reason, they provide the best evidence of efficacy and safety. The most rigorous RCTs utilize a placebo (inactive) control group and blinding (concealing active vs control assignment) to minimize bias in the interpretation of study results.
- ROM = range of motion
- SCIM = Spinal Cord Independence Measure is a measure of a person's ability to perform certain activities independently; i.e., an outcome measure of a research subject's independence in the performance of a variety of specific activities.
- SCI QL-23 = Spinal Cord Injury Quality of Life Questionnaire
- SF-36 = Short Form-36 is a patient-reported survey of health status. The SF-36 is commonly used as a measure of health-related quality of life (QoL).
- 6-Minute Walk Test = Distance that can be walked in 6 minutes.
- tDCS = transcranial direct current stimulation
- 10-Meter Walk Test = Time required to walk 10 meters.
- TRI-HFT = Toronto Rehabilitation Institute Hand Function Test: a clinical measure of hand function
- TUG = Timed Up and Go test
- UE = upper extremity
- Wernig Scale = A 6-item (0–5) classification scheme that describes the degree of walking independence with or without ambulatory aids.
- WISCI = Walking Index for Spinal Cord Injury is an ordinal scale measure for walking capabilities in persons with spinal cord injury.