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

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Sponsor/NCT	Intervention	Inclusion/ Exclusion Criteria	Treatment Timing & Follow-up	Enrollment	Phase of Study	Primary Outcome Other Outcomes	Comments
AOSpine N. Am Research Network, Reeve Foundation, Dept of Defense Rick Hansen Institute NCT01597518	Riluzole 2 x 100 mg by mouth or feeding tube the first 24 hours followed by 2 x 50 mg for the following 13 days after injury vs. placebo in acute SCI	18-75 yr Age C4-C8 AIS A, B, C	Acute SCI SCI≤12 hours F/U 6m	Began 8/2013 N. America Multicenter 351 subjects	Phase 2/3 RCT Double-Blind	Efficacy/Safety Change in ISNCSCI total motor score from baseline to 6months of F/U	Multicenter Phase2/ 3 trial of riluzole vs. placebo for improving motor recovery in acute SCI
Rick Hansen Institute U of Calgary Alberta Paraplegia Foundation NCT01828203	Twice Daily IV Minocycline vs. Placebo for over seven days All patients receive decompressive spine surgery and Blood Pressure management per protocol	≥16yr Age C0-C8 AIS A, B, C, D	Acute SCI SCI≤12 hours F/U 12m	Began 6/2013 Canada 248 subjects	Phase 3 RCT	Efficacy/Safety ISNCSCI Motor Score recovery from baseline to examination between 3m and 1yr post injury; ISNCSCI Sensory Scores AIS; SCIM; QoL: SF-36	800 mg initial dose tapered 100mg each dose to 400mg then continued twice daily x 7days
Ohio State Univ. NCT02524379	72 hour IV infusion of glyburide (RP-1127) started within 6 hours of SCI	18-70yr Age C4-C8 AIS A, B, C	Acute SCI SCI≤6hrs F/U 1yr	Began 8/2015 USA multisite 10 subjects	Phase n.s. Single Group Open Label	Adverse Events Preliminary Efficacy (n.s.)	Single group early phase safety study of IV glyburide in acute SCI
Vertex Pharmaceuticals NCT02669849	VX-210 (3mg or 9mg dose) in fibrin sealant applied to the dura at the time of spinal decompression/stabilization surgery within 72hr of SCI	14-75yr Age C4-6 Motor Level each side AIS A, B	Acute SCI SCI≥72hr F/U 6m	Began 2/2016 150 subjects	Phase 2/3 RCT Parallel Group Double Blind	ISNCSCI UEMS/Motor Level SCIM III CUE-T GRASSP AIS Pharmacokinetics	RCT to determine whether VX-210 delivered during spinal surgery is effective in neurological recovery and functional capacity in persons with acute SCI
Kringle Pharma, Inc NCT02193334	IT injection of 0.6mg Hepatocyte Growth Factor (HGF) vs. placebo starting at 72hr post injury, then weekly x5 weeks	18-75yr Age C4-C8 AIS A, B	Acute SCI SCI ≤72hr F/U 24wk	Began 6/2014 Japan 48 subjects	Phase 1/2 RCT Placebo Controlled	Safety/Efficacy Adverse Events ASIA Motor Score Change 24wk	Study of intrathecal HGF vs. placebo given within 72h then daily for 5 days
Jan Schwab, Elise Kroner Fresnius Foundation, Charite University NCT 02096913	Dolormin extra (ibuprofen) 2400mg daily (800mg 3 times per day) for 4 wks (6 subjects) or 12wks (6subjects)	18-65yr Age C4-T4 AIS A, B	Acute SCI 4d≤SCI≤21d F/U 6m	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 months in acute SCI also measuring ISNCSCI, spasticity and pain outcomes
Hotchkiss Brain Inst U of Calgary NCT02232165	Medical management of blood pressure to target of mean arterial pressure ≥65mmHg vs. ≥85mmHg for 7days following SCI	≥16yr Age C0-T12 AIS A, B, C No Central Cord	Acute SCI SCI≤12hr F/U 1yr	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

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St. Joseph's Hosp NCT02495545	CSF Drainage (target IT pressure 10mmHg) and elevation of Mean Arterial Pressure (MAP) with norepinephrine (goal 100-110 mmHg) vs. Elevation/maintenance of MAP alone with norepinephrine (goal 85-90mmHg) for 5d.	18-75yr Age C4-C8 AIS A, B, C	Acute SCI SCI≤24h F/U 180d	Began 10/2015 USA 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
Kessler Foundation; NIDRR; Acorda Therapeutics NCT01621113	Oral dalfampridine (Sustained release 4-aminopyridine) vs. placebo for 10 weeks in chronic motor incomplete SCI receiving locomotor therapy	18-70 yr Age C4-T10 AIS C, D	Chronic SCI SCI>12m F/U 22wks	Began 6/2012 New Jersey 46 subjects	Phase 2 RCT Double-Blind	Change in 6 minute walk test at 10 weeks and 22 weeks F/U	Test of whether dalfampridine improves walking outcomes in chronic motor incomplete SCI
Rehab Inst Chicago (RIC) NCT01753882	Escitalopram (Lexapro) 10mg PO Daily x 4 weeks vs Placebo in patients enrolled in gait training regimen (3x per wk for 6 wks—2 wks prior to initiation of study med, then 4 wks combined gait training and study med)	18-75yr Age SCI C1-T10 AIS C, D 1-9m post SCI	Subacute/Chronic 1m≤SCI≤9m F/U 10-12wk	Began 2/2012 Chicago 88 subjects	Phase 1 Randomized Double Blinded Crossover	Safety/Efficacy Modified Ashworth Berg Balance WISCI II Peak Treadmill Velocity 6 Minute Walk LEMS	Studying the combined effects of gait training and escitalopram on motor function and ↑ in locomotor capability
McMaster University NCT01904591	Dietary Supplementation with 50µgm Selenium and 400IU Vitamin E daily for 1 year	>18yr Age SCI>1yr	Chronic SCI SCI>1yr F/U 1yr	Began 10/2013 Hamilton, ON 10 subjects	Phase 1 Open Label	MRI Tractography Baseline compared to 1 year follow-up ISNCSCI	Study of dietary supplementation with selenium and Vitamin E in chronic SCI
Moleac Pte Ltd. NCT02537899	NeuroAiD (a "natural product" combining several Chinese herbal ingredients) given in oral capsule form for 6 months; combined with standard rehabilitation therapies	18-65yr Age AIS A, B	Acute/Subacute SCI 3d-4wk post SCI F/U 24m	Began 6/2015 Malaysia 30 subjects	Phase 4 Open Label Case Series	AIS ISNCSCI Motor/Sensory Scores SCIM SF-8 Adverse Events	Open label study of Chinese herbal supplement plus rehabilitation in acute/subacute SCI
Emory University 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	18-77yr Age C4-T12 AIS C, D	Chronic SCI SCI>12m F/U 4m	Began 10/2014 Atlanta 20 Subjects	Phase 1/2 RCT Double Blinded Placebo Controlled Crossover	Change in over ground walking speed and endurance	Repetitive Exposure of Intermittent Hypoxia to Enhance Walking Recovery in Persons With Chronic Spinal Cord Injury

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Emory University 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) sham with caffeine or placebo on Leg Function following SCI (Caffeine Sub-study)	18-77yr Age C2-T11 AIS C, D	Chronic SCI SCI>12m F/U 2weeks	Began 10/2014 Atlanta 20 Subjects	Phase 1/2 RCT Double Blinded Placebo Controlled Crossover	Change in over ground walking speed and endurance Muscle Strength Coordination Kinematics Force Production during walking	Study on the Effects of Caffeine and Low Oxygen Therapy on Leg Function in Human Spinal Cord Injury
Emory University US Dept of Defense NCT02632422	10 sessions of daily acute intermittent hypoxia (dAIH) vs. daily room air (dSHAM); ambulatory subjects in both groups will also receive 60 minutes of walking practice at a frequency of up to 5 days each week for 2 weeks	18-65yr Age C4-T11 Some motor function below neuro level AIS B, C, D	Subacute SCI SCI for 2-4m F/U 2weeks	Began 10/2015 Atlanta, GA 125 subjects	Phase n.s. RCT Parallel Group Double Blind	TUG 6 minute walk test 10 meter walk test Pain, Spasticity Hypertension Autonomic Dysreflexia incidence	RCT of daily acute intermittent hypoxia vs. sham (room air) in non-ambulatory and ambulatory subacute incomplete SCI to determine effect on recovery of walking function
Emory University NICHD NCT02323945	Effect of acute intermittent hypoxia (AIH, breathing air with low oxygen) vs. Room air (breathing air with normal oxygen) sham on Leg Function following SCI	18-77yr Age C2-T11 AIS C, D	Chronic SCI SCI>12m F/U 2weeks	Began 10/2014 Atlanta 44 Subjects	Phase 1/2 RCT Double Blinded Placebo Controlled Crossover	Change in over ground walking speed and endurance Muscle Strength Coordination Kinematics Force Production during walking BDNF, Apolipoprotein E Polymorphisms	Study to gain understanding of underlying mechanisms of AIH effect on Leg Function after SCI
University 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 spinal cord injury	18-65yr Age SCI C5-T12 (Thoracic cohort followed by Cervical Cohort) AIS A, B, C SCI≤3cm length	Chronic SCI SCI≥12m F/U 6m	Began 1/2015 Miami 10 Subjects	Phase 1 Single Group Open Label	Safety/Efficacy Change in ISNCSCI Exam from baseline to 12 months MRI Imaging of the Spinal Cord Neuropathic Pain measure Others: SCIM, FIM, Neurophysiology, autonomic, etc.	Study of the safety of autologous human Schwann cell (ahSC) transplantation in participants with chronic SCI receiving rehabilitation
Asterias Biotherapeutics NCT02302157	Surgical spinal cord implantation of embryonic stem cell-derived Oligodendrocyte Progenitor Cells (AST-OPC1). Dose escalation with sequential cohorts receiving an 2, 10, or 20 million AST-OPC1 at a single time-point 14-30 days after injury.	18-65yr Age C5-C7 AIS A	Subacute SCI 14-30 days post SCI F/U 1yr	Began 3/2015 USA multisite 13 subjects	Phase 1/2a Open Label	Safety Incidence of Adverse Events ISNCSCI UEMS Motor Level	Phase 1/2a Dose Escalation Study of AST-OPC1 in Subjects With Cervical Sensorimotor Complete SCI

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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 weeks of rehabilitation	16-65yr Age Chronic SCI Cervical level AIS B Stable neuro after 1 m rehab	Chronic SCI SCI≥12m F/U 12m after surgery	Began 8/2008 S. Korea 32 subjects	Phase 2/3 Single Group Open Label	Efficacy/Safety ASIA Motor Score ASIA Sensory Score EMG, Neurophysiology MRI Adverse events	Ongoing study of autologous BM derived Stem Cells followed by 4 weeks of rehabilitation
Chaitanya Hospital, Pune (Patient self-funded) NCT01833975	Intrathecal transplantation of Bone Marrow-derived autologous stem cell; 100 million cells/dose; 3 doses over 10 days	18-55yr Age SCI below C4 AIS A-D	Time post-SCI Not Specified F/U 6m	Began 3/2011 India 50 subjects	Phase 1/2 Single Group Open Label	Safety/Efficacy Improvement in Frankel score Improvement in ASIA (ISNCSCI)	Study the Safety and Efficacy of Bone Marrow Derived Autologous Cells for Treatment of SCI
Puerta de Hierro University Hospital NCT02570932	Lumbar puncture IT administration of expanded autologous adult bone marrow mesenchymal stem cells; 3 doses—one dose every 3 months	18-70yr Age SCI level n.s. AIS A, B, C, D	Chronic SCI Stable neuro≥6m F/U	Began 7/2015 Madrid, Spain 10 subjects	Phase 2 Single Group Open Label	IANR-SCIFRS Penn Spasm Frequency VAS Pain Outcome Neurotrophic Factors in CSF Adverse Events	Study of 3 IT injections of BM stem cells in chronic SCI
Hospital Sao Rafael NCT02152657	Autologous Mesenchymal Cells (Bone Marrow) transplanted into the spinal cord via transcutaneous injection (location n.s.)	18-65yr Age SCI below T8 AIS A	Chronic SCI>6m F/U 6m	Began 1/2015 Brazil 5 subjects	Phase 1/2 Single Group Open Label	MRI Sensory/motor examination LEMS/AIS change Urodynamics	Small pilot trial to study percutaneous Spinal Cord injection of Mesenchymal SC
Hospital Sao Rafael NCT02574572	Autologous bone marrow mesenchymal stem cell transplantation in patients with cervical chronic and complete spinal cord injury (location n.s.)	18-65yr Age C5-C7 AIS A	Chronic SCI≥12m F/U 12m	Began 10/2015 Brazil 10 subjects	Phase 1 Single Group Open Label	AE assessed by spinal cord MRI AIS Sensory Mapping Neuropathic Pain	Autologous Mesenchymal Stem Cells Transplantation in Subjects With Cervical Chronic Complete SCI
Hospital Sao Rafael NCT02574585	Autologous mesenchymal cells transplantation. Two percutaneous injections (location n.s.) of mesenchymal stem cells, with a 3-month interval between the injections; vs. randomly assigned control group without any specific intervention	18-65yr Age T1-L2 AIS A	Chronic SCI≥12m F/U 12m	Not yet recruit Brazil 40 subjects	Phase 2 RCT Parallel Group Open Label	AE assessed by spinal cord MRI AIS Sensory Mapping Neuropathic Pain	RCT for the evaluation of autologous mesenchymal stem cell transplantation in thoracolumbar chronic complete SCI
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.	5-50yr Age Level/AIS n.s.	Chronic SCI SCI≥6m, ≤60m	Began 1/2016 Jordan 50 Subjects	Phase 1/2 RCT Parallel Group Open Label	ISNCSCI Urine & Stool Incontinence QoL Independence Questionnaire Safety (n.s.)	Comparing transplantation of purified autologous bone marrow- vs. leukapheresis-derived stem cells for patients with chronic SCI
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	18-65yr Age T2-T11 AIS A	Chronic SCI 4m-48m post SCI F/U 18m	Began 6/2015 Sweden 27 subjects	Phase 1/2 Parallel Group RCT	Safety: Adverse Events MEP improvement	Rehabilitation-controlled RCT studying SC0806 (a biodegradable device with heparin-activated FGF1 and nerve implants)

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Sun Yat-Sen Univ. 3rd Affil. Hospital NCT02481440	IT administration of up to 1x 10^6 umbilical cord mesenchymal stem cells per kg, every month for 4 months	18-60yr Age SCI Level n.s. AIS A, B, C, D	Acute-Chronic SCI 2w-1yr post-SCI F/U 24m	Began 1/2014 China 44 subjects	Phase 3 Single Group Open Label	ISNCSCI ASIA score change EMG Electroneurophysiology Adverse Events	IT injection of umbilical cord blood mesenchymal stem cells
Chinese Acad. of Sci University of CAPF Soochow University NCT02510365	Collagen scaffold transplanted into spinal cord after acute spinal cord injury	18-65yr Age C5-T12 AIS A	Acute SCI SCI≤21d F/U 12m	Began 4/2015 Soochow, and Tianjin, China 10 subjects	Phase 1 Single Group Open Label	AIS SSEP, MEP Adverse Events	Functional Neural Regeneration Collagen Scaffold Transplantation in Complete Acute SCI
Chinese Acad. of Sci University of CAPF 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 spinal cord injury. All patients have surgical removal of spinal cord scar tissue, and have post-operative comprehensive rehabilitation	18-65yr Age C5-T12 AIS A	Chronic SCI Time after SCI n.s. F/U 24m	Began 1/2016 Tianjin, China 30 Subjects	Phase 1/2 RCT Parallel Group Double Blind	AIS SSEP/MEP FIM MRI Bladder/Bowel Function Safety/Tolerability/AE	Study to assess the efficacy & safety of mesenchymal stem cells or neural stem cells combined with NeuroRegen scaffold transplantation in patients with chronic SCI
Chinese Acad. of Sci PLA Gen Hospital NCT02688062	NeuroRegen Scaffold™ with bone marrow mononuclear cell transplantation vs. intradural decompression and adhesiolysis in persons with chronic SCI	18-60yr Age Thoracic Level AIS A	Chronic SCI Time after SCI n.s. F/U 24m	Began 1/2016 Beijing, China 22 subjects	Phase 1/2 RCT Parallel Group Double Blind	AIS SSEP/MEP FIM MRI Bladder/Bowel Function Safety/Tolerability/AE	RCT comparing NeuroRegen scaffold with BM mononuclear cells vs. intradural decompression with lysis of adhesions
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 spinal cord injury	16-70yr Age T2-T12 AIS A Can receive implant within 96h of SCI MRI contusion ≥4mm	Acute SCI Able to receive implant ≤96h after SCI F/U 6m	Began 4/2014 16 USA Centers 20 Subjects	Phase 3 Single Group Open Label	AIS Motor Scores/Sensory Scores SCIM III Bowel/Bladder Function Incidence of AE	Humanitarian Device Exemption (HDE) Probable Benefit Study to demonstrate safety and probable benefit in support of future studies and an HDE application with subsequent FDA approval
Washington U US Department of Defense NCT01714349	Brachialis branch to anterior interosseous nerve transfer	18-65yr Age Cervical SCI; No hand function; AIS A, B, C; SCI>6mos	Chronic SCI>6m F/U 24m	Began 10/2012 St. Louis, MO 20 subjects	Phase not specified; Single Group Open Label	Upper Extremity 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

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U British Columbia NCT01579604	Supinator branch to posterior interosseous nerve transfer	≥18yr Age Cervical SCI 12m>SCI>6m ICSH 0-5	Chronic SCI 12m>SCI>6 F/U 24m	Began 6/2012 Vancouver, BC 10 Subjects	Phase 4 RCT Open Label	Upper Extremity 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 Hospital 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.	18-60yr Age T1-T12 AIS A	Chronic SCI SCI ≥12m F/U 1yr	Began 7/2015 Kunming, China 30 Subjects	Phase n.s. RCT Parallel Group Single Blind	Kunming Locomotor Scale WISCI SCIM AIS Modified Ashworth Adverse Events, Pain	Surgical Decompression/Untethering Combined With Weight Bearing Rehabilitation in Chronic Spinal Cord Injury Subjects
Tokyo University NCT01485458	Early (<24h) vs. Delayed (>2wk) Decompression surgery for acute cervical SCI in patients with cervical canal stenosis without bony injury	20-79yr Age Cervical below C5 AIS C	Acute/Subacute Admitted within 48 hours of SCI 1yr F/U	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
Raboud University NCT01367405	Surgical Decompression Versus Conservative (non-surgical) Treatment in Incomplete SCI without spinal instability	≥18 yr Age Incomplete SCI without spinal instability	Acute SCI SCI≤24hr F/U 2yr	Began 10/2013 Netherlands 72 subjects—must speak Dutch	Phase n.s. RCT Parallel Group Open Label	Functional outcome at 2yr 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 NCT02673320	Randomized assignment to early (within 48hr) vs. delayed (at 15 days) spinal decompression surgery	≥18 yr Age C2-T1 AIS A-D Contusive SCI on MRI with narrow canal	Acute SCI SCI eligible for surgery within 48hrs F/U 2yr	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 48hr vs. surgery performed at 15 days

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 June 2, 2016 at which time the www.clinicaltrials.gov search found a total of 840 SCI trials. Of these, the status of 279 trials was known and listed as currently recruiting or not yet recruiting. The table includes 37 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.

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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://prsinfo.clinicaltrials.gov/fdaaa.html.

Terms/Abbreviations

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.

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.

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.

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 RCT's 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 RCT's utilize a placebo (inactive) control group and blinding (concealing active vs. control assignment) to minimize bias in the interpretation of study results.

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IV: intravenous—administration of a drug by vein

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

SQ: subcutaneous—administration of a drug by injection beneath the skin

F/U: follow-up

n.s.: not specified

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.

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 sub-components of the UEMS and the LEMS which are commonly analyzed and reported separately.

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.

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

Kunming Locomotor Scale: a 10-grade Roman numeral locomotion scoring system describing ability to stand, ability to walk, and required support/devices.

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.

FIM: the Functional Independence Measure was developed to measure the burden of care in persons who were not independent in ADL, 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.

EMG: the electromyogram refers to a physiological test of muscle and nerve function.

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GRASSP: 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

IANR-SCIFRS: the International Association of Neurorestoratology-Spinal Cord Injury Functional Rating Scale.

Penn Spasm Frequency Scale: a measure of spasticity based on frequency of spasm occurrence

VAS: Visual Analogue Scale—a scale commonly used to assess the severity of pain

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

Ashworth/Modified Ashworth: a scale used to measure spasticity severity

Barthel Index: a measure of performance in Activities of Daily Living (ADL) and Mobility

SF-36: the 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