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 June 6, 2018 Listing 44 Trials

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 USA, Canada, Australia, New Zealand 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
Vertex Pharmaceuticals NCT02669849	VX-210 (3mg or 9mg dose vs.placebo) in fibrin sealant applied to the dura at the time of spinal decompression/stabilization surgery within 72hr of SCI	14-75yr Age C4-7 Motor Level each side AIS A, B	Acute SCI SCI≥72hr F/U 6m	Began 2/2016 25 study centers US, Canada 150 subjects	Phase 2b/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
Eusol Biotech, Ltd NCT03229031	Intrathecal administration of ES 135 (rhFGF1) vs. placebo in patients who receive spinal surgery	18-65yr Age SCI level NS AIS A	time post SCI NS F/U 48wks	Began 4/2018 Taiwan 100 subjects	Phase 3 RCT Parallel Group Double Blind	ISNCSCI Motor Scores	Multicenter, Placebo-controlled Phase 3 RCT to Evaluate the Safety and Efficacy of intrathecal ES135 in Subjects with SCI receiving spinal surgery
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
Ohio State Univ. NCT02524379	12 doses of glyburide starting within 8 hours of SCI. Initial dose of 1.25 mg followed by 11 consecutive doses of 0.625 mg every 6 hrs over 72 hour period.	18-80yr Age C2-C8 AIS A, B, C	Acute SCI SCI≤8hrs F/U 1yr	Began 2/2017 Columbus, OH 10 subjects	Phase 1/2 Single Group Open Label	Adverse Events Pharmacokinetics Preliminary Efficacy (NS)	Single group early phase safety study of IV glyburide in acute SCI
Medical U. of Graz NCT03101982	Hyperbaric Oxygen (HBO) initiated within 24 hours of SCI given in 21 consecutive daily sessions at Medical University of Graz. Standard of Care Control subjects admitted to Paracelsus University Salzburg.	Age 16-70yrs Level NS AIS A, B, C, D	Acute SCI SCI≤24hrs F/U 1yr	Not yet begun Graz, Austria Salzburg, Austria 100 Subjects	Phase 2 Non-random Parallel Group Open Label	ISNCSCI Blood Testing MRI	Study of the effects of HBO on neurological impairment following acute SCI. 50 subjects in treatment group, 50 subjects in control group.

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Revised June 6, 2018 Listing 44 Trials

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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 San Antonio. TX 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 University Dept of Defense NCT02878850	Pharmacological management of blood pressure in persons with acute SCI; comparing BP kept in a higher range (85-90mmHg), vs. BP kept in a normal range (MAP 65-70mmHg) for 7 days	≥18yr Age C0-T8 AIS A, B No Central Cord No Penetrating Injury	Acute SCI Duration NS F/U 6m	Began 1/2017 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 Spinal Cord Injury, comparing 2 BP target ranges
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
University of British Columbia Rick Hansen Institute NCT01279811	Intravenous vasopressor drugs (norepinephrine or dopamine) initiated within to improve spinal cord perfusion pressure, initiated within 48 hours of injury and continued for 5 days with a daily 1 hour "crossover" protocol to compare the effectiveness of the two drugs	Age≥17yr C0-L1 AIS A, B, C	Acute SCI SCI≤48hrs F/U 1yr	Began 1/2011 North American Multicenter 100 subjects	Phase N/A Single Group Open Label	Spinal Cord Perfusion Pressure CSF biomarkers ISNCSCI Pain Questionnaire	Crossover study of the effect of vasopressor drugs to improve spinal cord perfusion pressure. Also collecting spinal fluid biomarkers to improve understanding of SCI and recovery.
University of Miami US DoD NCT02991690	Modest (33°C) intravascular hypothermia via Asius Icy CoolGuard® catheter inserted into the femoral vein. Patients will be cooled at a maximum rate (2-2.5°C/hr) until reaching target temp. (33°C) which will be maintained for 48hrs, then rewarmed at 0.1°C/hr until returned to normal temp. vs. Standard of Care control group	18-70yr Age Cervical SCI AIS A, B, C	Acute SCI SCI≤24h F/U 12m	Began 5/2017 USA Multicenter 120 subjects	Phase N/A Parallel Group RCT Open Label	AIS ASIA Motor Index FIM SCIM	Prospective Multi-center Case Controlled Study of Systemic Hypothermia in Acute Cervical SCI

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Revised June 6, 2018 Listing 44 Trials

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AUVA Trauma Center Meidling NCT03399968	Extracorporeal shockwave therapy (ESWT) at the injury level and 5 segments up and down of the spinal cord paravertebrally left and right vs. sham ESWT by positioning of the therapy head at the injury level without application of shockwaves	Age≥18yr T2-T1 AIS A stable neuro 6m	Chronic SCI SCI≥1yr F/U 24wks	Began 3/2015 Austria 25 Subjects	Phase N/A RCT Sham Control Parallel Group Double Blind	Gait Analysis (Lokomat) ISNCSCI Tardieu Spasticity Test Trunk Control-functional reach SCIM	Extracorporeal Shockwave Therapy (ESWT) to Improve Function in Chronic ASIA-A Patients
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
Spaulding Rehab Hospital 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	18-75yr Age C4-T12 AIS C, D	Chronic SCI SCI>12m F/U 4w	Began 10/2014 Atlanta 20 Subjects	Phase N/A RCT Double Blinded Placebo Controlled Crossover	Change in over ground walking endurance and speed	Repetitive Exposure of Intermittent Hypoxia to Enhance Walking Recovery in Persons With Chronic Spinal Cord Injury
Spaulding Rehab Hospital NICHD Wings For Life 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)	18-75yr Age C2-T11 AIS C, D	Chronic SCI SCI>12m F/U 2weeks	Began 10/2014 Cambridge, MA, USA 20 Subjects	Phase 1/2 RCT Double Blinded Placebo Controlled Crossover	10MWT Muscle Strength @ Ankle Coordination Kinematics Force Production during walking	Study on the Effects of Caffeine and Low Oxygen Therapy on Leg Function in Human Spinal Cord Injury
Spaulding Rehab Hospital 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, Cambridge, MA 125 subjects	Phase NS 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

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Revised June 6, 2018 Listing 44 Trials

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Spaulding Rehab Hospital NICHD Wings for Life NCT02323945	Effect of acute intermittent hypoxia (AIH, breathing air with low oxygen) on Leg Function following SCI. AIH with/without walking practice will be compared to AIH with/without ankle flexion torque practice	18-75yr Age C2-T11 AIS C, D	Chronic SCI SCI>12m F/U 2weeks	Began 10/2014 Cambridge, MA, USA 44 Subjects	Phase 1/2 RCT Double Blinded Placebo Controlled Crossover	Walking endurance 2MWT/6MWT Muscle Strength @ ankle Walking speed 10MWT	Study to gain understanding of underlying mechanisms of AIH effect on Leg Function after SCI
Shirley Ryan AbilityLab NCT03262766	Acute intermittent hypoxia (AIH) 90 seconds of 9-10% O2, alternating with 90 seconds of 21% (normal) O2; repeated up to 18 times per session each (up to 45 minute sessions). Testing 4 combinations of therapy: 1) AIH alone; 2) AIH *and* upper limb training; 3) sham AIH *and* upper limb training; 4) sham AIH alone. Upper limb training with Armeo Spring robotic device. Daily sessions for 5 days.	Age 18-70yr C2-T2 AIS C, D	Chronic SCI SCI>1yr F/U 6wks	Began 6/2017 Chicago 80 Subjects	Phase N/A RCT Sham Control Double Blind	Grip Strength Pinch Grip Box and Block Test 9 Hole Peg Test SCIM III GRASSP CUE	Daily Intermittent Hypoxia and Task-Specific Upper Limb Training in Persons with Chronic Incomplete SCI
University of Florida NCT03071393	Acute Intermittent Hypoxia (AIH) sessions of 15 brief (60-120 sec) exposures to low oxygen (9-15% inspired O_2) alternating with 15 brief exposures of ambient room air (21% inspired O_2). Two sessions at least 7 days apart: AIH or Sham (room air) randomly assigned with crossover. Inspired O_2 delivered via Hypoxico Hyp-123 device. Study to determine AIH effects on motor function after SCI.	Age 18-65yr SCI C4-T12 AIS NS	Chronic SCI SCI>6m F/U≥ 1week	Began 7/2017 Florida 30 Subjects	Phase N/A RCT Sham Control Crossover Double Blind	Neuromuscular Recovery Scale Maximum Inspiratory Pressure Maximum Expiratory Pressure Forced Vital Capacity EMG TUG 10MWT 6MWT	Sham controlled crossover RCT of the effects of a single session of AIH on motor function in persons with chronic SCI
Univ. of Miami US Dept of Educ. NCT03433599	Acute Intermittent Hypoxia (AIH) sessions of brief (60-90 sec) exposures to low oxygen (9-10% inspired O2) alternating with brief (60-90 sec) exposures of ambient room air vs. sham (Room Air) in combination with training either with Exoskeleton Rapael glove or standard UE Rehab training or no training	Age 18-70yr SCI C3-T1 AIS C, D	Chronic SCI SCI>6m F/U 12wks	Not yet begun Miami 125 Subjects	Phase N/A RCT Parallel Group Double Blind	Grip Strength 9-Hole Peg Test Pinch Strength Elbow Strength Box and Block Test GRASSP CUE-Q	Studying the effectiveness of daily AIH, coupled with massed practice training, to improve UE function in individuals with chronic incomplete cervical SCI

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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
Neuralstem, Inc. NCT01772810	Surgical injection of Neural Stem Cells into the area of SCI; 6 injections per patient; two dose cohorts 100,000 cells in 10µL/injection and 200,000 cells in 10µL/injection; patients receive immunosuppressive treatment for 3 months after implant	18-65yr Age Grp A: T2-T12 Grp B: C5-C7 AIS A Lives ≤500mi of Study Site	Chronic SCI 1yr≤SCI≤2yr F/U 5yr	Began 8/2014 San Diego, CA 8 subjects; now enrolling Grp B subjects	Phase 1 Open Label	Safety Incidence of Adverse Events Graft Survival (MRI evidence) Immune Suppress Effectiveness ISNCSCI exam	To determine safety of human spinal stem cell transplantation for treatment of paralysis and related SCI symptoms
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 6m≤SCI≤60m F/U 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

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Neurogen Brain and Spine Institute NCT02009124	Autologous Bone Marrow Mononuclear Cells administered by IT injection via lumbar puncture, followed by vigorous rehabilitation therapy	1-65yr Age SCI of any type	Duration NS F/U 6m	Began 8/2012 Mumbai, India 500 subjects	Phase 2 non-randomized Open Label Parallel Group	Change in symptoms of SCI FIM	Large Phase 2, Non-randomized, open label, parallel group trial of BM stem cells
Da Nang Hospital NCT02923817	Autologous Bone Marrow Mononuclear Cells administered by IT injection via lumbar puncture	20-60yr Age SCI Level NS AIS A, B	Subacute-Chronic SCI≥3wk to 1yr F/U 6m	Began 9/2016 Da Nang, Vietnam 30 subjects	Phase 2 Single Group Open Label	Safety/Adverse Events ISNCSCI Motor/Sensory AIS	Open label, single group study of bone marrow-derived mononuclear cells transplanted via lumbar puncture
Mayo Clinic NCT03308565	Single IT L4-5 level administration of 100 million autologous adipose-derived mesenchymal stem cells. The patient's adipose tissue is harvested from small abdominal or thigh incision, culture-expanded for 4-6 weeks, then transplanted via IT injection.	Age ≥18yrs SCI Level NS AIS A, B	Subacute-Chronic SCI≥2wk to 1yr F/U 96wks	Began 12/2017 Rochester, MN 10 subjects	Phase 1 Single Group Open Label	Safety/Adverse Events AIS MEP, SSEP MRI Lab Hematology/Chemistry	Autologous Adipose Derived Mesenchymal Stem Cells in the Treatment of Paralysis Due to Traumatic Spinal Cord Injury
Ferrer Internacional NCT02917291	Single intramedullary injection of FAB117-HC, a medicinal product containing human allogeneic adipose-derived adult mesenchymal stem cells in either 20 million or 40 million cell doses; Phase 2 includes untreated control group; treatment group receives highest tolerated dose from Phase 1	18-65yr Age T5-10 (Phase 1) T1-12 (Phase 2) AIS A (Phase 1), A, B (Phase 2)	Acute SCI Phase 1: 72-120hr Phase 2: 24-72hr F/U 12m	Began 12/2016 Spain 46 subjects	Phase 1/2 Randomized Parallel Group Double Blind	Safety/Adverse Events ISNCSCI SCIM III SSEP MEP	Study of medicinal product containing allogeneic adipose-derived adult mesenchymal stem cells pulsed with H2O2, injected into SCI during clinical decompressive spine surgery
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-10yrs 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)
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	18-65yr Age SCI Level NS AIS A, B, C, D	Acute-Chronic SCI>2wks F/U 24m	Began 1/2014 China 44 subjects	Phase 1/2 Single Group Open Label	ISNCSCI ASIA score change IANR-SCIRFS EMG Electroneurophysiology Adverse Events	IT injection of umbilical cord blood mesenchymal stem cells

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Sun Yat-Sen Univ. 3rd Affil. Hospital NCT03521336	IT administration of 1x 106 umbilical cord mesenchymal stem cells per kg, every month for 4 months vs. sham IT administration of saline every month for 4 months	18-65yr Age SCI Level NS AIS A, B, C, D	Subacute SCI 2w≤SCI≤2m F/U 12m	Began 1/2018 China 130 subjects	Phase 2 RCT Parallel Group Single Blind	ISNCSCI IANR-SCIRFS EMG Change in Residual Urine (US) Adverse Events	IT transplantation of umbilical cord mesenchymal stem cells in patients with sub-acute SCI
Sun Yat-Sen Univ. 3rd Affil. Hospital NCT03521323	IT administration of 1x 106 umbilical cord mesenchymal stem cells per kg, every month for 4 months vs. sham IT administration of saline every month for 4 months	18-65yr Age SCI Level NS AIS A, B, C, D	Early Chronic 2m≤SCI≤12m F/U 12m	Began 1/2018 China 92 subjects	Phase 2 RCT Parallel Group Single Blind	ISNCSCI IANR-SCIRFS EMG Change in Residual Urine (US) Adverse Events	IT transplantation of umbilical cord mesenchymal stem cells in patients with early stage chronic SCI
Sun Yat-Sen Univ. 3rd Affil. Hospital NCT03505034	IT administration of 1x 106 umbilical cord mesenchymal stem cells per kg, every month for 4 months	18-65yr Age SCI Level NS AIS A, B, C, D	Late Chronic SCI>12m F/U 12m	Began 1/2018 China 96 subjects	Phase 2 Single Group Open Label Cohort Study	ISNCSCI IANR-SCIRFS EMG Change in Residual Urine (US) Adverse Events	IT transplantation of umbilical cord mesenchymal stem cells in patients with late stage chronic SCI
Chinese Acad. Sci Univ. 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 NCT02352077	Surgical implantation of NeuroRegen scaffold with Bone Marrow Mononuclear Cells or Mesenchymal Stem Cells after localized SCI scarring excised; followed by comprehensive rehabilitation, psychological and nutritional treatment	18-65yr Age C5-T12 AIS A	Chronic SCI Duration NS F/U 12m	Began 1/2015 China 30 Subjects Enrolling by Invitation Only	Phase 1 Single Group Open Label	Safety/Tolerability/AE AIS SSEP/MEP FIM MRI Bladder/Bowel Function	NeuroRegen Scaffold™ With Bone Marrow Mononuclear Cells or Mesenchymal Stem Cells for Chronic Spinal Cord Injury Repair—enrolling by invitation only
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 Duration NS 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
Washington U NCT01899664	Upper Extremity Nerve Transfer Surgery. Unilateral surgery will be performed under general non-paralytic anesthesia and no-tourniquet conditions to allow for assessment of intraoperative nerve simulation responses	Age 18-60yrs Cervical SCI UE impairment Can access hand therapy program	Chronic SCI SCI>6mos Stable neuro impairment for 6mos F/U 3yr	Began 6/2012 St. Louis, MO 50 Subjects	Phase N/A Single Group Open Label	GRASSP Muscle Testing, ROM ISNCSCI SF-36 SCIM COPM	Study of the Surgical Treatment of Cervical Spinal Cord Injuries With Nerve Transfers to Restore Upper Extremity and Hand Function

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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 or central cord syndrome; SCI>6mos	Chronic SCI>6m F/U 24m	Began 10/2012 St. Louis, MO 20 subjects	Phase N/A 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
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>4m F/U 24m	Began 6/2012 Vancouver, BC 10 Subjects	Phase 4 RCT Parallel Group Open Label	Upper Extremity Strength (Manual Muscle Testing) Active Range of Motion DASH scale GRASSP	Study of early peripheral nerve transfer for improving UE strength in patients with tetraplegia
U of Texas Med Center, Houston NCT03451474	Upper extremity nerve transfer surgery followed by hand/occupational therapy to retrain motor skills	Age 18-65yr Cervical SCI AIS A, B, C ICSH 0-4 Lives in Houston area	Chronic SCI SCI>6m F/U 24m	Began 4/2018 Houston, TX 10 Subjects	Phase N/A Single Group Open Label	GRASSP Manual Muscle Testing UE UEMS EMG SCIM III DASH SF-36	Study for restoration of hand function utilizing Nerve Transfer Surgery in persons with chronic cervical SCI
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 F/U 1yr	Began 12/2011 Japan 100 subjects	Phase N/A RCT Open Label	ISNCSCI SCIM walking ability SF-36, Pain Symptom Inventory AE	Test of whether timing of spinal cord decompression is associated with neurological outcome in SCI without fracture/dislocation
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 begun France Multicenter 72 subjects	Phase N/A 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
Peking University People's Hospital NCT03103516	Early (≤24h) vs. Delayed (>24hr) epidural decompression spinal surgery. Group assignment determined by patient's condition and operation time; i.e. non-randomized trial	Age 16-85yrs SCI Level NS AIS NS	Acute SCI Time NS F/U 6m	Not yet begun Beijing China 200 Subjects	Phase N/A Non-random Parallel Group Single Blind	UEMS, LEMS AIS AE	Non-randomized trial comparing neurological outcomes in persons with acute SCI undergoing early vs. delayed epidural decompression

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Current SCI Clinical Trials of Drug, Cell, and Surgical Interventions to Improve Neurological and Related Functional Outcomes

Revised June 6, 2018 Listing 44 Trials

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 6, 2018 at which time the www.clinicaltrials.gov search found a total of 992 SCI trials. Of these, there were 273 interventional trials that are enrolling or not-yet-enrolling. Review of these 292 studies for those that are targeting improvement in neurological or related functional outcomes yielded the current list. The table includes 44 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, hypoxia, hypothermia, or hyperbaric oxygen; and 3) targeted sensorimotor neurological or related functional improvement of the spinal cord as outcome measures. Trials meeting these criteria are included if sufficient information is available on the clinicaltrials.gov webpages to adequately determine basic protocol design, the nature of the intervention, its delivery method, and relevant 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. The clinicaltrials.gov website is the largest repository of current and past clinical trials for all diseases and disorders—as of June 6, 2018 the registry contained information on 274,648 trials including research conducted in all 50 states in the USA and 204 countries. 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.**

More detailed information on individual trials may be accessed by using the NCT number found in the first column of the table. All trials registered with www.clinicaltrials.gov are assigned a registration number that begins with NCT (e.g. NCT01321333). Entering the NCT number into the search field of www.clinicaltrials.gov or www.google.com will access the webpage describing the trial, the study centers, and contact information in more detail. When an electronic version of the tables is used (e.g. when downloaded as a pdf file from www.scope-sci.org), the webpages describing a specific trial can be directly accessed by using the hyperlink (left Click to follow the link) of the NCT number in the table. Listing of a clinical trial on the clinicaltrials.gov website does not reflect an endorsement by SCOPE or the National Institutes of Health. Information appearing on the clinicaltrials.gov website is provided by study sponsors/investigators and is not verified by SCOPE or clinicaltrials.gov for scientific validity or relevance. Before volunteering to participate in a clinical trial, patients are urged to discuss all options with their healthcare provider and other trusted advisors.

Terms/Abbreviations

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: a scale used to measure spasticity severity

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

Box and Block Test: a test of manual dexterity

Central Cord Syndrome/Cervical Central Cord Syndrome: motor incomplete cervical SCI in which the upper extremities are significantly more impaired than the lower extremities

COPM: Canadian Occupational Performance Measure

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.

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.

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

F/U: follow-up

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

IANR-SCIFRS: the International Association of Neurorestoratology-Spinal Cord Injury Functional Rating Scale. Changes in motor and sensory scores assessed by IANR-SCIRFS scale (total score range from 0 to 51, higher values represent a better outcome)

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 which contains the cerebrospinal fluid (CSF)

IV: intravenous—administration of a drug by vein

Kinematics: analysis of movement

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

N/A: not applicable

NS: not specified

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

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.

Residual Urine: Changes in residual urine measured after voiding by ultrasound test (volume of urine in mL, lower values represent a better outcome)

ROM: Range of Motion

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.

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

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

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.

Tardieu test: test of spasticity by assessing muscle resistance to passive movement at both slow and fast speed.

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

9 Hole Peg Test: a test of manual dexterity

6MWT: 6 minute walk test. An assessment of the distance that the subject can walk in 6 minutes.

10MWT: 10 meter walk test. An assessment of the time required to walk 10 meters.