SCITrialsFinder.net - SCI Trials of Drug, Cell, and Surgical Interventions to Improve Functional Outcomes

Revised June 1, 2022 - Listing of 38 Trials

NCT ID	Sponsor	Intervention	Criteria	Status	Target Enrollment	Study Phase & Design	Primary Intervention Type	Primary Potential Benefit	Outcome Measures and Follow Up	Study Start Date	First Posted	LastUpdated	Location(s)
NCT04812431	S.Biomedics Co., Ltd.	Type: Biological, Name: Neural precursor cells derived from human embryonic stem cell line, Description: When the Dose Limiting Toxicity (DLT) is not presented in the first three subjects administered with PSA-NCAM(+) NPC, two additional patients are added to the clinical study.	• 18 to 65yrs • SCI 7-60 days • AIS A • SCI C4-C7	Recruiting	5	Phase: Phase 1. Phase 2, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Cell-based	General Health	• Adverse events • Blood pressure, body temperature, heart rate, respiratory rate • Hematology, chemistry and urinalysis values • Graft survival at the transplant site (MRI examination) • ASIA Damage Scale • ISNCSCI motor & sensory scores • Pain assessment • SCIM score F/U 72 weeks	September 2021	March 23, 2021	May 5, 2022	Seoul, South Korea
NCT04528550	Shanghai Changzheng Hospital	Intrathecal transplantation of autologous bone marrow-derived mononuclear cells through lumbar injection.	• Age 18-60 yrs • AIS A-D • SCI < 2 weeks • Traumatic SCI	Recruiting	45	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: None (Open Label)	Cell-based	General Health	• ISNCSCI • Adverse events • Motor Evoked Potentials (MEP) • Somatosensory Evoked Potentials (SSEP) • Residual urine test F/U 12 months	October 2020	August 27, 2020	July 7, 2021	Shanghai, China
NCT04520373	Mayo Clinic	Intrathecal injection of autologous, adipose derived mesenchymal stem cells	• Age ≥ 18 yrs • Traumatic SCI • AIS A, B • No contraindication to MRI scan	Recruiting	40	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Crossover Assignment, Masking: Quadruple	Cell-based	General Health	• ASIA sensory and motor function • Somatosensory evoked potentials • Neurogenic Bladder Symptom Score • Neurogenic Bowel Symptom Score • Cerebrospinal fluid composition • Pathologic mass at the spinal cord • Adverse events F/U 12 months	June 2020	August 20, 2020	May 5, 2022	Rochester, MN, USA
NCT03979742	StemCyte, Inc.	Umbilical Cord Blood (UCB) Mononuclear Cell transplant into injured spinal cord combined with either 6-weeks of oral lithium carbonate or placebo followed by the locomotor training for up to 6 hours a day, 6 days a week, for 3-6 months. Comparator group: no surgery, no transplant, no lithium, does get locomotor training	• Age 18-60 yrs • Level C5-T11 • AIS A • Chronic SCI • SCI ≥ 12 months	Recruiting	18	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: None (Open Label)	Cell-based	Standing/ Walking/ Mobility	• WISCI II • SCIM III • ISNCSCI • Kunming Locomotor Score • Pain • SSEP / MEP • MRI / DTI Tractography F/U 48 weeks	March 2022	June 7, 2019	May 16, 2022	Multicenter: New Jersey, USA; Hualien City, Taipei City, Taiwan;
NCT03935724	Neuroplast	Autologous Bone Marrow-derived stem cells (Neuro-Cells) or placebo, delivered intrathecally via lumbar puncture, 6-8 weeks after SCI. Subjects initially receiving placebo receive Neuro-Cells 32-34 weeks after SCI.	• Age 18-65 yrs • Level C6-T12 • AIS A, B, C • Subacute SCI • SCI 6-8 weeks	Recruiting	70	Phase: Phase 2/3, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Quadruple	Cell-based	General Health	• ISNCSCI • Motor Index Scores • AIS grade • Sensory Scores F/U 12 months	January 2022	May 2, 2019	March 2, 2022	Copenhagen, Denmark, Toledo, Spain
NCT03933072	Nicholls Spinal Injury Foundation	Autologous olfactory ensheathing cells (OECs) and olfactory nerve fibroblasts (ONFs) obtained from patient's olfactory bulb; autologous sural nerve harvest. Preparation of Glial Neuropatch. Microsurgical reconstruction of the transected spinal cord with Glial Neuropatch-nerve bridges	• Age 16-65 yrs • Level C5-T10 • AIS A • Complete transection of cord • In active rehab • Time post-SCI not stated	Recruiting	2	Phase: Phase 1. Phase 2, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Cell-based	Standing/ Walking/ Mobility	• ISNCSCI • Berg Balance • Deep Sensation, Proprioception • WISCI • SCIM III • MRI • Neurophysiology F/U 2-3 years	March 2016	May 1, 2019	November 23, 2021	Wroclaw, Poland
NCT02917291	Ferrer Internacional S.A.	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	• Age 16-70 yrs • Level T1-12 (Phase 1) • Level T1-12 (Phase 2) • AIS A (Phase 1), • AIS A, B (Phase 2) • Acute SCI (Phase 1: 72-120 hours, Phase 2: ≤ 96 hours)	Recruiting	48	Phase: Phase 1. Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Cell-based	General Health	• Safety / Adverse Events • ISNCSCI • SCIM III • SSEP • MEP F/U 12 months	December 2016	September 28, 2016	September 16, 2021	Multicenter: Spain
NCT01772810	Neuralstem Inc.	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	• Age 18-65 yrs • Grp A: Level T2-T12 • Grp B: Level C5-C7 • AIS A • Lives ≤ 500 miles of study site • Chronic SCI (1-2 years)	Recruiting	8	Phase: Phase 1, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Cell-based	Standing/ Walking/ Mobility	• Safety • Incidence of Adverse Events • Graft Survival (MRI evidence) • Immune Suppress Effectiveness • ISNCSCI exam F/U 5 years	August 2014	January 21, 2013	September 11, 2017	San Diego, CA, USA

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NCT05302999	MetroHealth Medical Center	Feasibility of Early Gabapentin as an Intervention for Neurorecovery	• Minimum 18 years old • Traumatic SCI; • All levels of SCI; • All severities of SCI, AIS A-D; • Age 18 years and older. • Agree to participate and start study drug within 120 hours' post-injury. • Adequate cognition and communication to provide informed consent, Exclusion Criteria: • No presence of moderate/severe traumatic brain injury (TBI) as defined by Glasgow Coma Score (GCS) < 13 at 120 hours' post-injury. • No documented use of gabapentinoids at the time of injury.	Recruiting	42	Phase: Phase 4, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Drug	General health	• Number of participants recruited • Adherence rate to drug treatment protocol • Number of occurrences of unblinding • Retention rate F/U 6 months	March 2022	March 31, 2022	March 31, 2022	Cleveland, Ohio, USA
NCT05217498	Spaulding Rehabilitation Hospital	Combining Low Oxygen Therapy and an Adenosine A2a Receptor Antagonist to Improve Functional Mobility After Spinal Cord Injury	• Age 18-75 years • Level C2-T12 with non-progressive etiology • motor-incomplete with visible volitional leg movement • SCI > 12 months • ability to advance one step overground without human assistance • No concurrent severe medical illness (i.e., infection, cardiovascular disease, ossification, recurrent autonomic dysreflexia, unhealed decubiti, and history of pulmonary complications) • No pregnant women because of the unknown effects of AIH on pregnant women and fetus • No history of seizures, brain injury, and/or epilepsy • No undergoing concurrent physical therapy • No diabetes • No cirrhosis • No caffeine and/or NSAID allergies or intolerances	Not yet recruiting	40	Phase: Phase 1/Phase 2, Primary Purpose: Treatment, Intervention Model: Crossover Assignment, Masking: Triple	Drug	standing/walking/ mobility	• 10MWT • 6MWT • TUG • Ankle Strength F/U 20 days	2022-09-01	February 1, 2022	June 27, 2022	Cambridge, MA, USA
NCT05041322	Spaulding Rehabilitation Hospital	Intake of Buspirone or a placebo drug. Subjects take 30 mg buspirone HCl (15 mg twice a day) for 14 Days.	• Age 18-50y • SCI > 24 months • SCI at or above T3 • AIS A-C • No heart disease • No high blood pressure(>140/90 mmHg or you are taking high blood pressure medication) • No orthostatic hypotension (symptomatic fall in blood pressure >30 mmHg when upright) • No chronic lung disease (COPD, bronchitis) • No intrathecal baclofen pump	Recruiting	30	Phase: Phase 2, Primary Purpose: Prevention, Intervention Model: Factorial Assignment, Masking: Double	Drug	General Health	• Pulmonary Function • Hypercapnic Ventilatory Response • Sleep Quality • Exercise Pulmonary Capacity F/U: 14 days	November 2020	September 13, 2021	January 21, 2022	Cambridge, MA, USA
NCT04988425	Shanghai Changzheng Hospital	The purpose of this study is to evaluate the safety and effectiveness of subcutaneous injection of TNFα monoclonal antibody cells for the treatment of traumatic acute spinal cord injury.	• Age 18 and 60 yrs • Traumatic spinal cord injury • AIS A-D • SCI <= 2 weeks • NO traumatic brain injury or peripheral nerve injury • NO spinal tumors, hematoma, myelitis • NO infectious disease, such as tuberculosis, HIV, hepatitis, syphilis, etc. • neurodegenerative diseases, or any neuropathies	Not yet recruiting	90	Phase: Phase 1. Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Single	Drug	General Health	• Change in AIS • adverse events • MEPs and SSEPs • residual urine test F/U: 12 months	2022-09-01	August 3, 2021	May 9, 2022	Shanghai, China
NCT04683848	Mitsubishi Tanabe Pharma Development America, Inc.	Intravenous administration of a humanized antibody (MT-3921)	• Age 18-70 yrs • AIS A-C • Level C4-C7 • UEMS ≤28 • BMI <40	Recruiting	72	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Quadruple	Drug	Arm/Hand Function	• Upper Extremity Motor Score (UEMS) • Spinal Cord Independence Measurement (SCIM) III score • GRASSP score • Spinal Cord Ability Ruler (SCAR)• Proportion of responders F/U 180 days	August 2021	December 24, 2020	July 5, 2022	Multicenter: USA, Canada, Japan
NCT04520178	University of Louisville	Oral intake of 5-Hydroxytryptophan in combination with Carbidopa	• Age 18-65 yrs • Traumatic SCI • SCI > 6 months • No history of seizures/epilepsy • No history of tumors	Recruiting	30	Phase: Phase 2/3, Primary Purpose: Basic Science, Intervention Model: Crossover Assignment, Masking: Double	Drug	General Health	• Motoneuron excitability (F wave) • Spinal excitability (H reflex) • Flexor reflex/spasms (Cutaneomuscular reflex) • Functional movement performance (Leg cycling task) • Blood analysis F/U 52 weeks	July 2020	August 20, 2020	August 30, 2021	Louisville, KY, USA

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NCT04475224	Kringle Pharma, Inc.	Intrathecal administration of KP-100IT, code of HGF (Hepatocyte Growth Factor)	• Age 18-89 yrs • SCI < 78 hours • Level C3-C8 • AIS A	Recruiting	25	Phase: Phase 3, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Drug	General Health	• Percentage of subjects with an improvement of at least two AIS • Frenkel score • Neurological level of injury • ASIA motor score • Blood and CSF analysis • Adverse events F/U 24 weeks	July 2020	July 17, 2020	March 8, 2021	Multicenter: Japan
NCT04460872	North Florida Foundation for Research and Education, Brooks Rehabilitation	Treadmill and overground walking training and testosterone enanthate via i.m. injection (100 mg/week)	• Male • Age ≥ 18 yrs • SCI > 12 months • Level C1-T12 • AIS B,C,D	Recruiting	21	Phase: Phase 2, Primary Purpose: Supportive Care Intervention Model: Parallel Assignment, Masking: None (Open Label)	Drug	Standing/ Walking/ Mobility	• Thigh muscle cross-sectional area • 6 min walk test (6MWT) • 10 meter walk test (10MWT) • Distal femur bone mineral density F/U 6 months	January 2021	July 8, 2020	September 5, 2021	Gainesville, FL, USA Jacksonville, FL, USA
NCT04458324	Spaulding Rehabilitation Hospital	6 months of functional electrical stimulation row training combined with receiving Buspirone Hydrochloride and non-ivasive ventilation	• Age 18-40 yrs • SCI 3-24 months • Level C1-T4 • AIS A,B,C • Wheelchair user • No history of epilepsy • No history of cancer	Recruiting	70	Phase: Phase 2, Primary Purpose: Treatment, Prevention Model: Factorial Assignment, Masking: Double	Drug	General Health	• Baseline aerobic exercise capacity • Baseline ventilation during exercise • Blood analysis F/U 6 months	December 2020	July 7, 2020	August 5, 2021	Cambridge, MA, USA
NCT04295538	AbbVie	Intravenous (IV) administration of drug (Elezanumab) and Placebo	• Age 18-75 yrs • Traumatic cervical SCI • Motor level of injury of C4, C5, C6, or C7 • UEMS ≤ 32. • AIS A-B • SCI ≤ 24 hours • No complete spinal cord transection	Recruiting	54	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Quadruple	Drug	Arm/Hand Function	• Upper Extremity Motor Score (UEMS) • SCIM III F/U 52 weeks	September 2020	March 4, 2020	June 21, 2022	Multicenter: USA, Japan, Australia, Canada, Spain
NCT04054414	Pharmazz, Inc.	Intravenous bolus dosing of PMZ-1620 (Sovateltide), on day 1, 3, and 6 along with standard of care treatment, vs. Normal Saline placebo with standard of care treatment	• Age 18-75 yrs • Level C5-S5 • AIS B, C, D • Acute SCI • SCI ≤ 48 hours	Recruiting	40	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Quadruple	Drug	General Health	• Adverse Events • Tolerability • ISNCSCI • WISCI • SCIM • MRI, CT F/U 90 days	January 2019	August 13, 2019	September 30, 2021	Multicenter: India
NCT04017767	University of Miami, Craig H Nielsen Foundation	Acute Intermittent Hypoxia (AIH) sessions (series of 15 and 90 second intervals of 9% inspired O2 alternating with 60 second 21% inspired O2) daily for 3 days. Two study groups: 1) subjects with chronic tetraplegia and moderate to severe obstructive sleep apnea (OSA) and chronic intermittent hypoxia (CHI), and 2) subjects with chronic tetraplegia without OSA	• Age ≥ 18 yrs • Chronic SCI • SCI ≥ 1 year • Non-progressive SCI • Level C5-8 • AIS C, D	Recruiting	30	Phase: N/A, Primary Purpose: Treatment Intervention Model: Parallel Assignment, Masking: N/A	Drug	General Health	• Pulmonary Function • Grip Strength • EMG • Biomarkers F/U 17 days	July 2021	July 12, 2019	July 21, 2021	Miami, FL, USA
NCT03935321	University of Zurich	Six intrathecal injections (given by spinal tap) of 45mg of NG-101 (anti-Nogo antibody) or placebo, given over 30 days	• Age 18-70 yrs • Level C1-C8 • AIS A, B, C, D • UEMS < 41 (out of 50) • Subacute SCI: Between 4 and 28 days	Recruiting	114	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Quadruple	Drug	Arm/Hand Function	• UEMS • ISNCSCI • SCIM III • WISCI • GRASSP • 10MWT, 6MWT • Bladder Diary F/U 168 days	May 2019	May 2, 2019	October 22, 2021	Multicenter: Europe
NCT03922802	Shirley Ryan AbilityLab	Transcutaneous spinal cord stimulation (tSCS) during walking rehabilitation, in combination with acute intermittent hypoxia.	• Age ≥ 18 yrs • SCI > 6 months • Level below C2 • AIS A, B, C, D • No epilepsy or a concussion within 6 months • No metal implants in the head or face • No implanted cardiac pacemaker or drug pump	Recruiting	36	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Crossover Assignment Masking: Single	Drug	Standing/ Walking/ Mobility	• 6 Minute Walk Test • 10 Meter Walk Test • Timed Up and Go Test F/U 12 months	October 2021	April 22, 2019	July 29, 2021	Chicago, IL, USA
NCT03911492	University of British Columbia	Insertion of a lumbar intrathecal catheter enabling active management of Spinal Cord Perfusion Pressure (SCPP) ≥65mmHg over 7 days post-injury by the use of vasopressor medications and CSF drainage. CSF will be collected for analysis of chemical indicators of injury severity.	• Age ≥ 17 yrs • Level C0-T12 • AIS A, B, C • Acute SCI • SCI ≤ 24 hours	Recruiting	100	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Drug	General Health	• ISNCSCI • Biomarkers in CSF & Blood • Spinal Cord Perfusion Pressure F/U 12 months	August 2019	April 11, 2019	December 3, 2021	Vancouver, BC, Canada Pittsburgh, PA, USA
NCT03833674	University of Florida, United States Department of Defense, Brooks Rehabilitation	5 daily sessions of AIH (short repetitive episodes of low oxygen (9% O2) alternating with normal oxygen (21% O2)), or sham (normal 21% O2), or respiratory strength training, or AIH combined with respiratory strength training. Participants receive all different treatment regimens in randomly assigned order.	• Age 18-70 yrs • Chronic SCI • SCI ≥ 1 yr (Level C1-T12; AIS B, C, D) OR • SCI ≥ 1 yr (Level C4-T12; AIS A; > 20% impairment of max inspiratory or expiratory pressure)	Recruiting	53	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Drug	General Health	• Maximal Inspiratory Pressure • Maximal Expiratory Pressure F/U 60 days	August 2020	February 7, 2019	November 5, 2021	Jacksonville, FL, USA

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NCT03780829	VA Office of Research and Development	Repetitive AIH vs. Sham AIH combined with exercise (bimanual massed practice training) and/or the drug D-cycloserine or sham drug.	• Age 18-80 yrs • Chronic SCI • SCI ≥ 1 yr • Level C8 and above • Veteran • Finger Flex and Abd strength 1-4 • Grasp small objects; precision index to thumb	Recruiting	175	Phase: Early Phase 1, Primary Purpose: Treatment, Intervention Model: Crossover Assignment, Masking: Double	Drug	Arm/Hand Function	• Grip Strength (dynomometer) • Pinch Strength (pinch gauge) • Motor Evoked Potential Amplitude F/U 12 weeks	February 2020	December 19, 2018	March 31, 2022	Hines, IL, USA
NCT03644277	Shirley Ryan AbilityLab	Random assignment to one of 5 treatment groups: daily acute intermittent hypoxia therapy (AIH) vs. sham AIH, with-or-without massed practice UE training; with-or-without Rapael Glove (robotic rehabilitation device)-administered UE training. Study designed to determine the effectiveness of these interventions in improving UE function in persons with chronic incomplete SCI.	• Age 18-75 yrs • Chronic SCI • SCI > 1yr • Level C2-T1 • AIS not stated • At least one hand has some grasp ability (GRASSP Prehension Ability score ≥ 2)	Recruiting	125	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Drug	Arm/Hand Function	• GRASSP F/U 3 months	July 2018	August 23, 2018	May 5, 2022	Multicenter: USA
NCT03643770	Shirley Ryan AbilityLab	Acute Intermittent Hypoxia (AIH)—short duration (< 2 min) exposures to reduced oxygen levels (~10% inspired oxygen) alternating with exposure to air with normal oxygen levels (~21% inspired oxygen) vs. sham AIH, in combination with-or-without upper extremity training using Armeo Spring (gravity support exoskeleton, to evaluate changes in upper extremity function.	• Age 18-75 yrs • Chronic SCI • SCI ≥ 6 months • Level C1-T1 • AIS not stated	Recruiting	92	Phase: Early Phase 1, Primary Purpose: Diagnostic Intervention Model: Single Group Assignment, Masking: Double	Drug	Arm/Hand Function	• GRASSP • 9-hole peg test • Grip Strength F/U 4 weeks	November 2018	August 23, 2018	June 25, 2021	Chicago, IL, USA
NCT03433599	Shirley Ryan AbilityLab , U.S. Department of Education	Repeated 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 upper extremity rehabilitation training or no training	• Age 18-85 yrs • Chronic SCI (≥ 6 months) • Level above L2 • AIS A, B, C, D • Ability to produce a visible precision grip with one hand and/or perform some small wrist extension and flexion • Ability to perform a smalldorsiflexion and hip flexion	Recruiting	125	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Drug	Arm/Hand Function	• GRASSP • 10 Meter Walk Test • Motor evoked potentials (TMS) • EMG F/U 1 hour	April 2020	February 14, 2018	June 30, 2022	Chicago, IL, USA
NCT03101982	Medical University of Graz	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 16-70 yrs • Level not stated • AIS A, B, C, D • Acute SCI (≤ 24 hours)	Not yet recruiting	100	Phase: Phase 2, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: None (Open Label)	Drug	General Health	• ISNCSCI • Blood Testing • MRI F/U 1 year	December 2022	April 5, 2017	March 17, 2022	Graz, Austria Salzburg, Austria
NCT02878850	Oregon Health and Science University	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	• Age ≥ 18 yrs • Level C0-T8 • AIS A, B, C • No central cord syndrome • No penetrating injury • Acute SCI • Duration not stated	Recruiting	152	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Single	Drug	Standing/ Walking/ Mobility	• ASIA motor score change • ASIA sensory score change • SCIM III • Pain Scores • QoL Satisfaction Score • Cardiovascular Adverse Events F/U 6 months	April 2017	August 25, 2016	May 24, 2022	Multicenter: USA
NCT02632422	Spaulding Rehabilitation Hospital	10 sessions (5/wk for 2 wks) 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 5 days each week for 2 weeks	• Age 18-70 yrs • Level C3-L5 • Some motor function below neuro level • AIS A, B, C, D • Subacute to chronic SCI (2-12 months)	Recruiting	125	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Drug	Standing/ Walking/ Mobility	• TUG • 6 minute walk test • 10 meter walk test • Pain • Spasticity • Hypertension • Autonomic Dysreflexia F/U 2 weeks	October 2015	December 16, 2015	May 11, 2022	Atlanta, GA, USA Cambridge, MA, USA
NCT02323945	Spaulding Rehabilitation Hospital	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	• Age 18-75 yrs • Chronic SCI (≥ 12 months) • Level C2-T11 • AIS C, D	Recruiting	44	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Crossover Assignment, Masking: Quadruple	Drug	Standing/ Walking/ Mobility	• Walking endurance 2MWT / 6MWT • Muscle Strength (ankle) • Walking speed 10MWT F/U 2 weeks	October 2014	December 24, 2014	June 27, 2022	Cambridge, MA, USA
NCT02274116	Spaulding Rehabilitation Hospital	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. Five 38 minute treatment sessions per week for 2 weeks.	• Age 18-75 yrs • Level C2-L5 • AIS C, D • Chronic SCI (> 6 months)	Recruiting	20	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Crossover Assignment, Masking: Quadruple	Drug	Standing/ Walking/ Mobility	• Change in over ground walking endurance (6MWT) and speed (10MWT) F/U 4 weeks	October 2014	October 24, 2014	June 27, 2022	Cambridge, MA, USA
NCT04936620	St George's, University of London	Expansion Duroplasty	• Age ≥16 yrs • Level C2 - T1 • Traumatic SCI • AIS A-C • Deemed to require and be suitable for surgery that includes laminectomy by local surgeon • Surgery within 72 hours of traumatic spinal cord injury	Not yet recruiting	222	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: Double	Surgery	General Health	• AIS • capabilities of upper extremity questionnaire • WISCI-II • SCIM III • SF-36 • adverse events • mortality F/U 12 months	July 2021	June 23, 2021	June 23, 2021	Multicenter: United Kingdom

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NCT04276181	Göteborg University	This is a study comparing combined upper extremity nerve transfer/tendon transfer patient outcomes to patients with only tendon transfer surgery	• Age 15-55 yrs • Level C5-C7 • SCI ≤ 12 months	Recruiting	80	Phase: N/A, Primary Purpose: N/A, Intervention Model: N/A, Masking: N/A	Surgery	Arm/Hand Function	• Grasp and release (cylinder test and GRT) • Grip strength • Pinch strength F/U 1 year	January 2020	February 19, 2020	March 17, 2022	Mölndal (Sweden)
NCT04023591	Washington University School of Medicine	Upper extremity nerve transfer surgery followed by 1-2/week X 48 months of Occupational Therapy/Hand Therapy for motor re-education	• Age 18-65 yrs • Chronic SCI (3-36 months) • AIS A, B • 3 m of non-op rehab therapy • Stable neurological exam • ICSH 0-4	Recruiting	70	Phase: N/A, Primary Purpose: N/A, Intervention Model: Single Group Assignment, Masking: None (Open Label)	Surgery	Arm/Hand Function	• Upper Extremity Strength (Manual Muscle Testing) • Dynamometry • DASH • SCI-QoL • GRASSP	April 2020	July 17, 2019	September 8, 2021	Multicenter: USA, Canada
NCT02991690	University of Miami, United States Department of Defense	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	• Age 18-70 yrs • Acute SCI (≤ 24 hours) • Cervical Level • AIS A, B, C	Recruiting	120	Phase: Not Applicable, Primary Purpose: Treatment, Intervention Model: Parallel Assignment, Masking: None (Open Label)	Surgery	General Health	• AIS • ASIA Motor Index • FIM • SCIM F/U 12 months	August 2017	December 13, 2016	March 17, 2022	Multicenter: USA
NCT02673320	Nantes University Hospital	Randomized assignment to early (within 48hr) vs. delayed (at 15 days) spinal decompression surgery	• Age ≥ 18 yrs • Acute SCI • SCI eligible for surgery within 48 hours • Level C2-T1 • AIS A-D • Contusive SCI on MRI with narrow canal	Recruiting	72	Phase: Not Applicable, Primary Purpose: Other Intervention Model: Parallel Assignment, Masking: None (Open Label)	Surgery	Standing/ Walking/ Mobility	• ISNCSCI • WISCI II • SCIM III • SF-36 • MRI • Adverse events / Complications F/U 2 years	July 2016	February 3, 2016	June 13, 2022	Multicenter: France

This table is abstracted from the clinical trial registration website www.clinicaltrials.gov using the search term "Spinal Cord Injuries" and is updated periodically. The most recent update occurred June 1, 2022 at which time the www.clinicaltrials.gov search found a total of 1,497 SCI trials. Of these, there were 410 interventional trials that are enrolling or not-yet-enrolling. Review of these 410 studies for those that are targeting improvement in neurological or related functional outcomes yielded the current list. The table includes 38 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, hyperbaric oxygen, low energy extracorporeal shock wave therapy, or near infrared laser light; 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 1, 2022 the registry contained information on 421,079 trials including research conducted in all 50 states in the USA and 219 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).

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 clinicaltrials.gov 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.

SCITrialsFinder.net - SCI Trials of Drug, Cell, and Surgical Interventions to Improve Functional Outcomes

Revised June 1, 2022 - Listing of 38 Trials

NCT ID	Sponsor	Intervention	Criteria	Status	Target Enrollment	Study Phase & Design	Primary Intervention Type	Primary Potential Benefit	Outcome Measures and Follow Up	Study Start Date	First Posted	LastUpdated	Location(s)

Terms/Abbreviations

• AIH: Acute Intermittent Hypoxia. Short duration (<2 min) exposure to breathing reduced oxygen concentration levels (~10% inspired oxygen), with alternating exposures to breathing air with normal oxygen concentration (~21% inspired oxygen).
This intervention is commonly delivered with a breathing mask device as a series of multiple brief hypoxic exposures alternating longer breathing exposure to "room air" with normal oxygen content.

• 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 without sensory function in the lowest sacral segments) 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-how many blocks a person can grasp and transfer in one minute.

• 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.

• ESWT: extracorporeal shock wave therapy. Delivery of sound wave energy to the spinal cord using a transducer applied to the skin (extracorporeal i.e. outside of the body).

• FIM: 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 subject's independence.

• 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).

• HDE: Humanitarian Device Exemption is a U.S. Food & Drug Administration (FDA) application that, if successful, authorizes the applicant to market a Humanitarian Use Device (HUD) subject to certain profit and use restrictions.

• HUD: Humanitarian Use Device is a designation of the U.S. FDA for medical devices intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 persons in the United States per year.
HUDs cannot be sold for profit, except in narrow circumstances, and they can only be used in a facility after an Institutional Review Board has approved their use in that facility except in certain emergencies.

• 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.

• IRB: Institutional Review Board is a multidisciplinary group that has been formally designated by an institution such as a hospital to review, approve and monitor biomedical research involving human subjects.

• ISAFSCI: International Standards to document remaining Autonomic Function after 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 SCI 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).
These trials usually do not include a comparison control group, and 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), timing (when and how), effect of the intervention on the body (what does it do, beneficial or harmful).
These trials commonly utilize multiple study centers, many subjects, and a randomized control group to provide direct information about efficacy & safety of the intervention. Phase 2 trials enable refinement of how to administer the intervention and how to measure its beneficial effects.
3: Phase 3 trials are conducted using the refined protocols developed from Phase 2 trials. They are often termed "pivotal" studies because they are sufficiently well-designed and rigorously conducted that their results, if positive, can be used for regulatory approval (e.g. FDA).
These trials almost always enroll large numbers of subjects (hundreds+), use multiple study centers, and a randomized control group design (placebo control and double blinding). 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.

• Pharmacokinetics: study of the absorption, distribution, metabolism, and excretion of drugs; commonly involving periodic sampling of bodily fluids (e.g. blood, serum, CSF, urine) to determine drug concentration changes over time.

• 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 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

• 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 ISNCSCI that include the ASIA Motor Index Score (TMS) and the sub-components of the UEMS and the LEMS which are commonly analyzed & reported separately.

• Tardieu Scale: 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.