Phase 1 Studies:

Safety Study of Human Spinal Cord-derived Neural Stem Cell Transplantation for the Treatment of Chronic SCI

NCT Number: NCT01772810
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury (SCI)
Interventions: Drug: Human spinal cord stem cells.
Sponsor/Collaborators: Neuralstem Inc.
Gender: All
Age Groups: Adult
Phases: Phase 1
Enrolment: 8
Funded By: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety Study | Intervention Model: Single Group Assignment | Masking: None (Open Label) | Primary Purpose: Treatment
Other IDs: NS2010-1
First Received: January 14, 2013
Start Date: August 2014
Completion Date: December 2022
Last Updated: September 11, 2017
Last Verified: September 2017
Acronym: SCI
Results First Received: No Study Results Posted
Primary Completion Date: July 2018
Outcome Measures: Adverse events and clinically significant laboratory abnormalities | Graft survival in the transplant site determined by MRI (for Group A) and via autopsy, if one is completed.
URL: https://ClinicalTrials.gov/show/NCT01772810

Monoaminergic Modulation of Motor Function in Subacute Incomplete Spinal Cord Injury (SCI)
NCT Number: NCT01753882
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: Lexapro | Drug: Placebo
Sponsor/Collaborators: Shirley Ryan AbilityLab | Rehabilitation Institute of Chicago
Gender: All
Age Groups: Adult | Senior
Phases: Phase 1
Enrolment: 88
Funded By: Other
Study Types: Intervventional
Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Crossover Assignment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor) | Primary Purpose: Treatment
Other IDs: STU00056589
First Received: December 6, 2012
Start Date: February 2012
Serotonergic Modulation of Motor Function in Subacute and Chronic SCI

NCT Number: NCT01788969

Recruitment: Active, not recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Drug: Lexapro | Drug: Placebo

Sponsor/Collaborators: Shirley Ryan AbilityLab | Rehabilitation Institute of Chicago

Gender: All

Age Groups: Adult

Phases: Phase 1

Enrolment: 42

Funded By: Other

Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Crossover Assignment | Primary Purpose: Treatment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)

Other IDs: STU00014259

First Received: February 7, 2013

URL: http://ClinicalTrials.gov/show/NCT01753882
Start Date: June 2005
Completion Date: December 2017
Last Updated: December 26, 2016
Last Verified: December, 2016

Results First Received: No Study Results Posted

Primary Completion Date: December 2016 (Final data collection date for primary outcome measure)

Outcome Measures: Walking Index for Spinal Cord Injury (WISCI II) | Volitional Strength | Gait kinematics | Fastest possible walking velocity over ground (FV; m/s) | Six minute walking distance (m) | Lower Extremity Motor Scores (LEMS) | Modified Ashworth of knee extensors/flexors (ModAsh) | Spinal Cord Assessment Tool for Spasticity (SCATS) | Peak Treadmill Velocity

URL: https://ClinicalTrials.gov/show/NCT01788969

Safety Study of Ibuprofen to Treat Acute Traumatic Spinal Cord Injury

NCT Number: NCT02096913
Recruitment: Completed
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: Dolormin® extra (Ibuprofen) | Drug: Dolormin® extra (Ibuprofen)
Sponsor/Collaborators: Jan M. Schwab, MD, PhD | Else Kröner Fresenius Foundation | Charite University, Berlin, Germany
Gender: All
Age Groups: Adult
Phases: Phase 1
Enrolment: 12
Funded By: Other
Study Types: Interventional
Study Designs: Allocation: Non-Randomised | Endpoint Classification: Safety Study |
**Intervention Model:** Single Group Assignment  |  **Primary Purpose:** Treatment  |  **Masking:** None (Open Label)

Other IDs:  
Ibuprofen-SCI-Safety|2011-000584-28

First Received:  
March 24, 2014

Start Date:  
June 2013

Completion Date:  
April 2016 (final data collection date for primary outcome measure)

Last Updated:  
October 30, 2017

Last Verified:  
October 2017

Acronym:  
Results First Received:  
No Study Results Posted

Primary Completion Date:  
September 2017

Outcome Measures:  
Number of patients with severe gastroduodenal bleedings as a measure of safety  |  Spasticity on the Modified Ashworth Scale (MAS)  |  Pain on the Neuropathic Pain Scale (NPS)  |  International standards for neurological classification of spinal cord injury (ISNCSCI) - ASIA impairment scale (AIS) change from baseline  |  Neurological motor function on the ISNCSCI/ASIA motor scores change from baseline  |  Neurological sensory function on the ISNCSCI/ASIA sensory score change from baseline  |  Number of participants with adverse events as a measure of safety and tolerability  |  Ibuprofen levels in plasma  |  Ibuprofen levels in cerebrospinal fluid (CSF)

URL:  
http://ClinicalTrials.gov/show/NCT02096913

**Assessing feasibility, safety and efficacy of IVIg therapy in patients with acute traumatic spinal cord injury**

ACTRN Number:  
12616001385437

Universal Trial Number:  
U1111-1187-9726

Title:  
Assessing feasibility, safety and efficacy of IVIg therapy in patients with acute traumatic spinal cord injury

Recruitment:  
Not yet recruiting

Study Results:  
No Results Available

Conditions:  
Spinal cord injury

Interventions:  
Privigen, i.e. liquid human Immunoglobulin preparation (10% w/v), will be administered intravenously in two doses. The first dose will be
given within 12 hours of acute traumatic cervical or thoracic spinal cord injury. The second dose will be administered the following day. Each dose will be calculated to 1g/kg of the patient's body weight.

Sponsor/Collaborators: CSL Behring AG Switzerland, University of Queensland

Gender: All

Age Groups: Adult | Senior – Maximum age 65 years

Phases: Phase 1

Enrolment: Anticipated sample size - 40

Funded By: Other

Study Types: Interventional

First Received: 23 September 2016

Start Date: February 15, 2017

Completion Date: -

Last Updated: July 7, 2017

Last Verified: July 2017

Acronym: IVIgSCI

Results First Received: No Study Results Posted

Primary Completion Date: 31 December 2019

Outcome Measures: To obtain exploratory data on the efficacy of IVIg infusion in patients with acute traumatic spinal cord injury. The functional outcome will be assessed via:

a) ASIA examinations (standard neurological assessment tool) to assess neurological (sensory and motor) impairment at set intervals post-accident

b) SCIM (Spinal Cord Independence Measure) questionnaires, which assess both function and independence.

URL:
https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371550&isReview=true
Transplantation of Autologous Adipose Derived Stem Cells (ADSCs) in Spinal Cord Injury Treatment

NCT Number: NCT02034669
Recruitment: Status unknown as information has not been verified lately
Study Results: No Results Available
Conditions: Acute Spinal Cord Injury
Interventions: Device: Laminectomy | Device: Intradural space | Device: Intrathecal | Device: Intravenous
Sponsor/Collaborators: Tri Phuoc Biotechnology JSC
Gender: All
Age Groups: Adult
Phases: Phase 1 | Phase 2
Enrolment: 48
Funded By: Other
Study Types: Interventional
Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Effacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: TP-VD-2012
First Received: January 6, 2014
Start Date: February 2013
Completion Date: March 2015
Last Updated: January 10, 2014
Last Verified: January 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: December 2014
Outcome Measures: Number of Participants with adverse events after transplantation. | Changes of spinal cord edema in the MRI at the lesion site | Urinary and bowel function Improvement | Muscle contraction force measurement | Significant clinical improvement in ASIA impairment scale and general condition.
URL: http://ClinicalTrials.gov/show/NCT02034669
Study of Human Central Nervous System Stem Cells (HuCNS-SC) in Patients with Thoracic Spinal Cord Injury

NCT Number: NCT01321333
Recruitment: Completed
Study Results: No Results Available
Interventions: Biological: HuCNS-SC cells
Sponsor/Collaborators: StemCells, Inc.
Gender: All
Age Groups: Adult
Phases: Phase 1 | Phase 2
Enrolment: 12
Funded By: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: CL-N02-SC
First Received: March 21, 2011
Start Date: March 2011
Completion Date: April 2015
Last Updated: June 16, 2015
Last Verified: June 2015
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: April 2015
Outcome Measures: Types and frequencies of adverse events and serious adverse events
URL: https://ClinicalTrials.gov/show/NCT01321333
Phase I/II Study of KP-100IT in Acute Spinal Cord Injury

CT Number: NCT02193334

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injuries

Interventions: Drug: KP-100IT | Drug: Placebo

Sponsor/Collaborators: Kringle Pharma, Inc.

Gender: All

Age Groups: Adult | Senior

Phases: Phase 1 | Phase 2

Enrolment: 48

Funded By: Industry

Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)

Other IDs: KP-100-ND002

First Received: June 27, 2014

Start Date: June 2014

Completion Date: October 2018

Last Updated: October 5, 2016

Last Verified: March 2015

Acronym: null

Results First Received: No Study Results Posted

Primary Completion Date: March 2018

Outcome Measures: Number and degree of adverse events | Change of ASIA (American Spinal Injury Association) motor score from baseline at 24 weeks | Change of ASIA motor score from baseline at 12-weeks | Time-dependent change of ASIA motor score from baseline | Time-dependent change of ASIA sensory score from baseline | Time-dependent grade change of modified Frankel scale from baseline | Time-dependent change of P-100 concentration in plasma and cerebrospinal fluid

URL: http://ClinicalTrials.gov/show/NCT02193334
Safety and Feasibility Study of Cell Therapy in Treatment of Spinal Cord Injury

NCT Number: NCT02237547
Recruitment: Withdrawn
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Biological: Intravenous and intrathecal human umbilical cord tissue derived mesenchymal stem cells and bone marrow mononuclear cells

Sponsor/Collaborators: Translational Biosciences
Gender: All
Age Groups: Adult
Phases: Phase 1 | Phase 2
Enrollment: 0
Funded By: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: No Masking
Other IDs: CNEI-2014-TBS-UCMSC-SCI001
First Received: September 9, 2014
Start Date: September 2014
Completion Date: October 2019
Last Updated: August 10, 2017
Last Verified: August 2017
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2019
Outcome Measures: Number of patients with adverse events | Number of subjects with a change in American Spinal Injury Association (ASIA) score from baseline | Number of subjects with a change in Frankel Scale score from baseline

URL: http://ClinicalTrials.gov/show/NCT02237547
Spinal Cord Neuromodulation for SCI

NCT Number: NCT02313194
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Cervical Spinal Cord Injury | Tetraparesis | Tetraplegia
Interventions: Device: Epidural Stimulation
Sponsor/Collaborators: University of California, Los Angeles
Gender: All
Age Groups: Adult | Senior
Phases: Phase 1 | Phase 2
Enrolment: 12
Funded By: Other
Study Types: Intervventional
Other IDs: 12-001416
First Received: December 5, 2014
Start Date: July 2013
Completion Date: July 2018
Last Updated: January 26, 2016
Last Verified: January 2016
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2018
Outcome Measures: Assessment of arm/hand function
URL: http://ClinicalTrials.gov/show/NCT02313194
Dose Escalation Study of AST-OPC1 in Spinal Cord Injury

NCT Number: NCT02302157
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Cervical Spinal Cord Injury | Spine Injury | Spinal Cord Trauma
Interventions: Biological: AST-OPC1
Sponsor/Collaborators: Asterias Biotherapeutics, Inc.
Gender: All
Age Groups: Adult | Senior
Phases: Phase 1 | Phase 2
Enrollment: 35
Funded By: Industry
Study Types: Intervventional
Study Designs: Endpoint Classification: Safety Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: No Masking (Open Label)
Other IDs: AST-OPC1-01
First Received: November 24, 2014
Start Date: March 2015
Completion Date: December 2018
Last Updated: December 13, 2017
Last Verified: December 2017
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: December 2018
Outcome Measures: Number of adverse events within 1 year (365 days) that are related to AST-OPC1 injection | Neurological function as measured by upper extremity motor scores and motor level on International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) examinations at 30, 60, 90, 180, and 365 days after injection of AST-
Safety and Preliminary Efficacy Of Fab117-HC in Patients with Acute Traumatic Spinal Cord Injury

NCT Number: NCT02917291
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Acute Traumatic Spinal Cord Injury
Interventions: Drug: FAB117-HC | Other: Control group | Drug: FAB117-HC
Sponsor/Collaborators: Ferrer Internacional S.A. | Histocell S.L.
Gender: All
Age: 18 Years to 65 Years (Adult)
Phases: Phase 1 | Phase 2
Enrolment: 46
Funded By: Industry | Other
Study Types: Interventional
Other IDs: FAB117-CT-01
First Received: September 20, 2016
Start Date: December 2016
Completion Date: January 2020
Last Updated: February 23, 2017
Last Verified: February 2017
Acronym: SPINE

Results First Received: No Study Results Posted

Primary Completion Date: April 2019

Outcome Measures: Number of adverse events as a measure of safety and tolerability of a single dose of FAB117-HC when administered by intramedullary injection into the injured spinal cord | Changes from baseline in neurological function using the International Standards for Neurological Classification of SCI (ISNCSCI) scale, examinations at 24h, 72h, 7d, 14d, 28d, 90d and 360 days after injection of FAB117-HC|Changes from baseline in the functional assessment of Spinal Cord Independence Measure (SCIM III)|Changes from baseline in Somatosensory-Evoked Potentials (SSEP) electrophysiological assessment test. Changes from baseline in Motor-Evoked Potentials (MEP) electrophysiological assessment test. Changes from baseline in nerve conduction velocities electrophysiological assessment test

URL: https://ClinicalTrials.gov/show/NCT02917291

Intrathecal Administration of Expanded Wharton’s Jelly Mesenchymal Stem Cells in Chronic Traumatic Spinal Cord Injury

NCT Number: NCT03003364

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury, Chronic

Interventions: Drug: XCEL-UMC-BETA | Drug: Placebo

Sponsor/Collaborators: Banc de Sang i Teixits | Hospital de Neurorehabilitació Institut Guttmann | Recerca Clínica S.L. | Syntax for Science

Gender: All

Age: Adult

Phases: Phase 1 | Phase 2

Enrolment: 10

Funded By: Other | Industry

Study Types: Interventional
Study Designs: Allocation: Randomised | Intervention Model: Crossover Assignment | Masking: Double Blind (Participant, Care Provider, Investigator, Assessor) | Primary Purpose: Treatment

Other IDs: XCEL-SCI-01

First Received: December 14, 2016
Start Date: December 27, 2016
Completion Date: April 2020
Last Updated: May 5, 2017
Last Verified: May 2017
Acronym: XCEL-SCI-01

Results First Received: No Study Results Posted
Primary Completion Date: March 2018

Outcome Measures: Incidence of treatment-emergent adverse events | Extent and severity of a patient's spinal cord injury | Motor electrophysiology assessment | Somatosensory electrophysiology assessment | Electrical nerve stimulation on pain perception | Mictorial dysfunction | Anal sphincter integrity | Neuropathic pain | Spasticity | Functionality | Quality of life | Urinary disorder | Size injury | Presence of allogeneic cells | Immunology

URL: https://ClinicalTrials.gov/show/NCT03003364

Improving Bladder Function in SCI by Neuromodulation

NCT Number: NCT02331979
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Device: Electromagnetic Neuromodulation
Sponsor/Collaborators: University of California, Los Angeles
Gender: Male
Age Groups: Adult
Phases: Early Phase 1
Enrolment: 24
Funded By: Other
Study Types: Interventional
Study Designs: Allocation: Non-Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: 14-000932
First Received: January 3, 2015
Start Date: September 2015
Completion Date: October 2018
Last Updated: January 27, 2016
Last Verified: January 2016
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: October 2018
Outcome Measures: Urine flow and volume
URL: https://ClinicalTrials.gov/show/NCT02331979

Spinal Cord Injury Neuroprotection with Glyburide
NCT Number: NCT02524379
Title: Glyburide Opportunity for Spinal Cord Injury Protection
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injuries
Interventions: Drug: RP-1127
Sponsor/Collaborators: Ohio State University
Gender: All
Age Groups: Adult | Senior
Phases: Phase 1 | Phase 2
Enrolment: 10
Funded By: Other
Study Types: Interventional
Study Designs: Endpoint Classification: Safety Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: 2014H0335
First Received: August 13, 2015
Start Date: February 14, 2017
Completion Date: February 2020
Last Updated: March 27, 2017
Last Verified: March 2017
Acronym: SCING
Results First Received: No Study Results Posted
Primary Completion Date: August 2017
Outcome Measures: The number of patients experiencing adverse events after administration of RP-1127 [ Time Frame: 1 year post treatment ]
URL: https://ClinicalTrials.gov/show/NCT02524379

Phase 2 Studies:

Treatment of Cervical Spinal Cord Injury with Imatinib - a Safety and Feasibility Study
NCT Number: NCT02363361
Recruitment: Unknown
Study Results: No Results Available
Conditions: Cervical Spinal Cord Injury
Interventions: Drug: Imatinib
Sponsor/Collaborators: Professor Mikael Svensson, MD PhD | Karolinska University Hospital
Gender: All
Age Groups: Adult | Senior
Phases: Phase 2
Enrolment: 10
Funded By: Other
Study Types: Interventional
Study Designs: Endpoint Classification: Safety Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: EudraCT no 2014-002170-36
First Received: February 3, 2015
Start Date: March 2015
Completion Date: December 2015
Last Updated: February 9, 2015
Last Verified: February 2015
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: December 2015
Outcome Measures: Change in levels of Imatinib in plasma and cytokines in serum day 1-3, 7, 10, 14, 16, 19 | Adverse events
URL: http://ClinicalTrials.gov/show/NCT02363361

Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of SUN13837 Injection in Adult Subjects with Acute Spinal Cord Injury (ASCI)

NCT Number: NCT01502631
Recruitment: Completed
Study Results: No Results Available
Conditions: Acute Spinal Cord Injury
Interventions: Drug: SUN13837 injection | Drug: Placebo
Sponsor/Collaborators: Daiichi Sankyo Inc.

Gender: All

Age Groups: Child | Adult | Senior

Phases: Phase 2

Enrolment: 62

Funded By: Industry

Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)

Other IDs: ASBI 603

First Received: December 27, 2011

Start Date: January 2012

Completion Date: March 2015

Last Updated: August 23, 2016

Last Verified: August 2016

Acronym: null

Results First Received: No Study Results Posted

Primary Completion Date: March 2015

Outcome Measures: Comparison of the proportion of SUN13837 treated subjects and placebo-treated subjects who are defined as responders. | Comparison of means in the SCIM III self-care subscale score in responders

URL: https://ClinicalTrials.gov/show/NCT01502631

Testosterone Plus Finasteride Treatment After Spinal Cord Injury

NCT Number: NCT02248701

Recruitment: Recruiting

Study Results: No Results Available
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<td>Drug: testosterone enanthate, finasteride</td>
<td>Other: placebo</td>
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<td>Change in body composition</td>
<td>Change in neuromuscular function</td>
<td>Change in metabolic profile</td>
<td>Changes in muscle cross-sectional area</td>
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<td>URL:</td>
<td><a href="http://ClinicalTrials.gov/show/NCT02248701">http://ClinicalTrials.gov/show/NCT02248701</a></td>
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Stem Cell Therapy in Spinal Cord Injury

NCT Number: NCT02009124
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury

Interventions: Biological: Autologous bone marrow mononuclear cell transplantation
Sponsor/Collaborators: Neurogen Brain and Spine Institute

Gender: All
Age Groups: Child | Adult
Phases: Phase 2
Enrolment: 500
Funded By: Other
Study Types: Interventional
Study Designs: Allocation: Non-Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: None (Open Label)

Other IDs: NGBSI-03
First Received: December 2, 2013
Start Date: August 2012
Completion Date: December, 2018
Last Updated: September 13, 2017
Last Verified: September 2017
Acronym: null

Results First Received: No Study Results Posted
Primary Completion Date: June 2018
Outcome Measures: Change in clinical symptoms of spinal cord injury after 6 months| Functional independence measure (FIM)

URL: https://ClinicalTrials.gov/show/NCT02009124
Fesoterodine for Amelioration of Autonomic Dysreflexia (AD) Following Spinal Cord Injury (SCI)

NCT Number: NCT02676154
Title: Fesoterodine for Amelioration of Autonomic Dysreflexia (AD) Following Spinal Cord Injury (SCI)
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Autonomic Dysreflexia
Interventions: Drug: Fesoterodine
Sponsor/Collaborators: University of British Columbia | Pfizer | International Collaboration On Repair Discoveries (ICORD) | Vancouver Coastal Health
Gender: All
Age Groups: Adult
Phases: Phase 2
Enrolment: 20
Funded By: Other | Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Efficacy Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: H15-02364|WI207218
First Received: January 27, 2016
Start Date: February 2016
Completion Date: October 2017
Last Updated: November 1, 2016
Last Verified: November 2016
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: February 2017
Outcome Measures: Number of participants that experience a decrease in severity of autonomic dysreflexia (AD) from baseline following 12-weeks of study
medication. Number of participants that experience a decrease in the frequency of autonomic dysreflexia (AD) episodes from baseline following 12-weeks of study medication. Number of participants that experience an improvement from baseline of self-reported severity and frequency of AD as reported with the Autonomic Dysreflexia Health Related-Quality of Life (AD HR-QoL) questionnaire and reflected by a decrease in score. An improvement from baseline of self-reported bladder incontinence as reported with the Incontinence Quality of Life (I-QoL) questionnaire and reflected with an increase in score. An improvement from baseline of cognitive function as evaluated with the Montreal Cognitive Assessment scale (MoCA) and reflected with a total score at or greater than 26. An improvement from baseline in bowel stool outcomes as reported with the Bristol Stool Scale. An improvement from baseline in the ability of the bladder to stretch in response to filling of the bladder as indicated by urodynamic studies (UDS) parameters of bladder volume and pressure on the detrusor muscle.

URL: https://ClinicalTrials.gov/show/NCT02676154

Riluzole in Spinal Cord Injury Study

NCT Number: NCT01597518
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: Riluzole | Drug: Placebo

Sponsor/Collaborators: AOSpine North America Research Network | AOSpine International | Christopher Reeve Paralysis Foundation | Department of Defense | Rick Hansen Institute

Gender: All
Age Groups: Adult | Senior
Phases: Phase 2 | Phase 3
Enrolment: 351
Funded By: Other | Industry | U.S. Fed
Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Efficacy Study | Intervention Model: Parallel Assignment | Masking: Double Blind (Participant, Investigator, Outcomes Assessor) | Primary Purpose: Treatment
Other IDs: SPN-12-001
First Received: May 10, 2012
Start Date: August 2013
Completion Date: December 2018
Last Updated: June 5, 2017
Last Verified: June 2017
Acronym: RISCIS
Results First Received: No Study Results Posted
Primary Completion Date: December 2018
Outcome Measures: Change in ISNCSCI Total Motor Score between 180 days and baseline
URL: http://ClinicalTrials.gov/show/NCT01597518

**Study to Assess the Efficacy and Safety of VX-210 in Subjects with Acute Traumatic Cervical Spinal Cord Injury**

NCT Number: NCT02669849
Title: Study to Assess the Efficacy and Safety of VX-210 in Subjects with Acute Traumatic Cervical Spinal Cord Injury
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Cervical Spinal Cord Injury
Interventions: Drug: VX-210 | Drug: Placebo
Sponsor/Collaborators: Vertex Pharmaceuticals Incorporated
Gender: All
Age Groups: Child | Adult | Senior
Phases: Phase 2 | Phase 3
Enrolment: 150
Funded By: Industry
Study Types: Interventional
Other IDs: VX15-210-101
First Received: January 21, 2016
Start Date: February 2016
Completion Date: June 2018
Last Updated: October 12, 2017
Last Verified: October 2017
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: June 2018
Outcome Measures: Change from baseline in upper extremity motor score (UEMS) | Spinal Cord Independence Measure (SCIM) III Self-Care subscore | Capabilities of Upper Extremity Test (CUE-T) score | Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP) Quantitative Prehension score | American Spinal Injury Association Impairment Scale (AIS) grade conversion | Motor level change using the ISNCSCI Exam | Pharmacokinetic (PK) parameters of VX-210: tmax (time of the maximum concentration) | Pharmacokinetic (PK) parameters of VX-210: Cmax (maximum observed concentration) | Pharmacokinetic (PK) parameters of VX210: AUC (Area Under plasma Concentration )
URL: https://ClinicalTrials.gov/show/NCT02669849

Clinical Trial Using Bone Marrow-derived Mononuclear Cells for Spinal Cord Injury
NCT Number: NCT02923817
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injuries
Interventions: Biological: Transplantation of autologous bone marrow-derived mononuclear cells by lumbar injection
Sponsor/Collaborators: Da Nang Hospital | Kitano Hospital | Translational Research Informatics Center, Kobe, Hyogo, Japan
Gender: All
Age: 20 Years to 60 Years (Adult)
Phases: Phase 2
Enrolment: 30
Funded By: Other
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study | Intervention Model: Single Group Assignment | Masking: Open Label | Primary Purpose: Treatment
Other IDs: DNHSCI124HP
First Received: October 3, 2016
Start Date: September 2016
Completion Date: June 2019
Last Updated: January 9, 2017
Last Verified: January 2017
Acronym: DNH
Results First Received: No Study Results Posted
Primary Completion Date: December 2018
Outcome Measures: Safety profile and adverse effects of the procedure | Motor function | Sensory function | ASIA Impairment Scale
URL: https://ClinicalTrials.gov/show/NCT02923817

Phase 3 Studies:

Mean Arterial Blood Pressure Treatment for Acute Spinal Cord Injury

NCT Number: NCT02232165
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Acute Spinal Cord Injury
Interventions: Other: Hypotension avoidance | Other: Induced hypertension
Efficacy and Safety of Growth Hormone Treatment in Spinal Cord Injury

NCT Number: NCT01329757
Recruitment: Unknown
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: GH | Drug: Placebo
Sponsor/Collaborators: Hospital Nacional de Parapléjicos de Toledo | Ministerio de Salud y Políticas Sociales (Ministry of Health)

Gender: All
Age Groups: Adult | Senior
Phases: Phase 3
Enrolment: 76
Funded By: Other
Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor) | Primary Purpose: Treatment

Other IDs: FHNPC-T001
First Received: April 4, 2011
Start Date: April 2011
Completion Date: November 2015
Last Updated: January 9, 2015
Last Verified: January 2015
Acronym: GHSCI

Results First Received: No Study Results Posted
Primary Completion Date: November 2015
Outcome Measures: Motor Score of the American Spinal Injury Association (ASIA) scale | ASIA | ASIA sensory score | Spasticity | Pain | Independence Measures and Quality of life | Neurophysiological Measures | Safety

URL: http://ClinicalTrials.gov/show/NCT01329757

Minocycline in Acute Spinal Cord Injury (MASC)

CT Number: NCT01828203
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injuries
Interventions: Drug: Minocycline | Drug: Placebo | Procedure: Surgical spinal cord decompression | Procedure: Maintenance of minimum mean arterial pressure (MAP)

Sponsor/Collaborators: Rick Hansen Institute Canada Inc. | University of Calgary | Alberta Paraplegic foundation

Gender: All

Age Groups: Child | Adult | Senior

Phases: Phase 3

Enrolment: 248

Funded By: Other

Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Efficacy Study | Intervention Model: Parallel Assignment | Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor) | Primary Purpose: Treatment

Other IDs: RHI-1005

First Received: April 5, 2013

Start Date: June 2013

Completion Date: June 2018

Last Updated: October 29, 2014

Last Verified: October 2014

Results First Received: No Study Results Posted

Primary Completion Date: June 2018

Outcome Measures: ASIA Motor Recovery | ASIA sensory recovery | Spinal cord Independence measure (SCIM) | Short Form 36 (SF-36) | ASIA impairment grade

URL: http://ClinicalTrials.gov/show/NCT01828203
Onabotulinumtoxin A (onaBoNT-A) Versus Oral Oxybutynin ER

NCT Number: NCT01050114
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Overactive Bladder
Interventions: Drug: onaBoNT-A | Drug: Oxybutynin ER
Sponsor/Collaborators: Christopher Patrick Smith | Baylor College of Medicine
Gender: All
Age Groups: Adult | Senior
Phases: Phase 3
Enrolment: 36
Funded By: Other
Study Types: Interventional
Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Double Blind (Participant, Care Provider, Investigator, Outcomes Assessor)
Other IDs: 11-09-10-04 (BCM H-26296) | H-26296
First Received: January 11, 2010
Start Date: August 2013
Completion Date: July 2018
Last Updated: August 29, 2016
Last Verified: August 2016
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: July 2018
Outcome Measures: Primary endpoint | The utility of urinary inflammatory markers as statistically significant predictors of treatment response.
URL: http://ClinicalTrials.gov/show/NCT01050114
Dysport® Treatment of Urinary Incontinence in Adults Subjects with Neurogenic Detrusor Overactivity (NDO) Due to Spinal Cord Injury or Multiple Sclerosis - Study 2

NCT Number: NCT02660359

Title: Dysport® Treatment of Urinary Incontinence in Adults Subjects with Neurogenic Detrusor Overactivity (NDO) Due to Spinal Cord Injury or Multiple Sclerosis - Study 2

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Urinary Incontinence | Overactive Bladder


Sponsor/Collaborators: Ipsen

Gender: All

Age Groups: Adult | Senior

Phases: Phase 3

Enrolment: 408

Funded By: Industry

Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Triple (Participant, Care Provider, Investigator)

Other IDs: D-FR-52120-223

First Received: January 14, 2016

Start Date: July 2016

Completion Date: October 2021

Last Updated: December 22, 2017

Last Verified: December 2017

Acronym: CONTENT2

Results First Received: No Study Results Posted

Primary Completion Date: September 2019
Outcome Measures: Change in weekly number of UI episodes | Proportion of subjects with no episodes of UI | Change in incontinence quality of life (I-QoL) total summary score

URL: https://ClinicalTrials.gov/show/NCT02660359

The INSPIRE Study: Probable Benefit of the Neuro-Spinal Scaffold for Treatment of AIS A Thoracic Acute Spinal Cord Study

NCT Number: NCT02138110
Recruitment: Active, not recruiting
Study Results: No Results Available
Conditions: Traumatic Acute Spinal Cord Injury
Interventions: Device: PLGA Poly-L-Lysine Scaffold
Sponsor/Collaborators: InVivo Therapeutics
Gender: All
Age Groups: Adult
Phases: Phase 3
Enrolment: 20 (estimated)
Funded by: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety Study | Intervention Model: Single Group Assessment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: InVivo-100-101
First Received: May 1, 2014
Start Date: April 2014
Completion Date: null
Last Updated: September 22, 2017
Last Verified: July 2017
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: September 2017

Outcome Measures: Incidence of Adverse Device Effects of any kind/seriousness. | AIS score changes from baseline at 1 month, 2 months, 3 months, 6 months and 12-months post implantation.

URL: https://ClinicalTrials.gov/show/NCT02138110

Phase 4 Studies:

Botox for Neurogenic Detrusor Overactivity and the Prevention of Autonomic Dysreflexia Following SCI

NCT Number: NCT02298660
Recruitment: Unknown status
Study Results: No Results Available
Conditions: Autonomic Dysreflexia
Interventions: Drug: BOTOX
Sponsor/Collaborators: Rick Hansen Institute
Gender: All
Age Groups: Adult
Phases: Phase 4
Enrollment: 40
Funded By: Other
Study Types: Interventional
Study Designs: Endpoint Classification: Efficacy Study | Intervention Model: Single Group Assignment | Primary Purpose: Prevention | Masking: Open Label
Other IDs: Rick Hansen Institute
First Received: September 17, 2012
Start Date: April 2013
Completion Date: January 2015
Last Updated: November 19, 2014
Last Verified: November 2014
Acronym: null
Results First Received: No Study Results Posted
Primary Completion Date: January 2015

Outcome Measures: Assess the efficacy of 200 U intradetrusor injected Botox on amelioration of episodes of autonomic dysreflexia (AD) in individuals with chronic spinal cord injury one month following treatment during urodynamics | The blocking of AD during 24-hour ambulatory blood pressure monitoring with daily catheterizations. | Cost analysis of BOTOX treatment on AD following six months of treatment. | The impact of BOTOX and blocking of AD response on enhanced quality of life (QOL) and incontinence health related QOL.

URL: http://ClinicalTrials.gov/show/NCT02298660

Spinal Cord Injury - Assessing Tolerability and Use of Combined Rehabilitation and NeuroAiD

NCT Number: NCT02537899
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: NeuroAiD
Sponsor/Collaborators: Moleac Pte Ltd.
Gender: All
Age Groups: Adult
Phases: Phase 4
Enrolment: 30
Funded By: Industry
Study Types: Interventional
Study Designs: Endpoint Classification: Safety/Efficacy Study | Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label
Other IDs: SATURN2015
First Received: August 27, 2015
Start Date: June 2015
Completion Date: December 2018
Last Updated: August 28, 2015
Last Verified: August 2015
Acronym: SATURN

Results First Received: No Study Results Posted
Primary Completion Date: December 2016

Outcome Measures:
- Spinal cord injury severity based on American Spinal Injury Association Impairment Scale
- Motor recovery based on American Spinal Injury Association Impairment Scale motor score
- Number of patients experiencing adverse events
- Sensory recovery based on American Spinal Injury Association Impairment Scale sensory score
- Functional state based on Spinal Cord Independence Measure
- Quality of life based on Short Form-8 Health Survey

URL: https://ClinicalTrials.gov/show/NCT02537899

**Prevention of Bladder Dysfunction in Acute Spinal Cord Injury**

NCT Number: NCT01698138
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injuries | Urinary Bladder, Overactive
Interventions: Drug: Onabotulinumtoxin A | Drug: Placebo
Sponsor/Collaborators: Oslo University Hospital | Sunnaas Rehabilitation Hospital

Gender: All
Age Groups: Adult | Senior
Phases: Phase 4
Enrolment: 20
Funded By: Other
Study Types: Interventional

Study Designs: Allocation: Randomised | Endpoint Classification: Efficacy Study | Intervention Model: Parallel Assignment | Primary Purpose: Treatment | Masking: Double Blind (Participant, Care Provider, Investigator)

Other IDs: 2012 / 1151

First Received: September 26, 2012

Start Date: September 2012

Completion Date: December 2020

Last Updated: February 7, 2017

Last Verified: February 2017

Acronym: BOT-SCI

Results First Received: No Study Results Posted

Primary Completion Date: December 2018

Outcome Measures: Presence of neurogenic detrusor over-activity during cystometry, defined as contractions with amplitudes above 40 cm H2O. Urodynamic parameters | Quality of life (QOL) in the treated group compared to the placebo group 12 months after first treatment. Occurrence of complications.

URL: http://ClinicalTrials.gov/show/NCT01698138

No Phase listing: