SpinalCure Australia

Tuesday 9th January, 2018

U.S. National Institutes of Health & Australian/New Zealand Clinical Trial Registry Database Records for Current Clinical Drug Trials

'Improving Functional Outcomes in Spinal Cord Injury'

Summary Report, Part 2

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 Asssignment | 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: Interventional

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

Last Updated: June 16, 2016

Last Verified: June 2016

Results First Received: No Study Results Posted

Primary Completion Date: July 2017

Outcome Measures: Walking Index for Spinal Cord Injury (WISCI II) | Peak treadmill velocity | 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)

URL: http://ClinicalTrials.gov/show/NCT01753882

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

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/Efficacy 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

Conditions: Thoracic Spinal Cord Injury | Spinal Cord Injury | Spinal Cord Injury Thoracic | Spinal Cord Trauma

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: Interventional

Study Designs: Allocation: Non-Randomised | Endpoint Classification: Safety/Efficacy Study| Intervention Model: Single Group Assignment | Primary Purpose: Treatment | Masking: Open Label

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 recuiting

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: Interventional

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-

OPC1

URL: http://ClinicalTrials.gov/show/NCT02302157

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

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

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
Outcomes	
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 | Mictional 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

Conditions: Spinal Cord Injury | Spinal Cord Injuries | Trauma, Nervous System | Wounds and Injuries | Central Nervous System Diseases | Nervous System Diseases | Spinal Cord Diseases | Gonadal Disorders | Endocrine System Diseases | Hypogonadism | Genital Diseases, Male

Interventions: Drug: testosterone enanthate, finasteride | Other: placebo

Sponsor/Collaborators: Department of Veterans Affairs | University of Florida

Gender: Male

Age Groups: Adult | Senior

Phases: Phase 2

Enrolment: 30

Funded By: U.S. Fed | Other

Study Types: Interventional

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

Other IDs: B1449-R|1I01RX001449-01A1

First Received: September 22, 2014

Start Date: January 16, 2016

Completion Date: June 1, 2019

Last Updated: December 18, 2017

Last Verified: December 2017

Acronym: null

Results First Received: No Study Results Posted

Primary Completion Date: May 31, 2019

Outcome Measures: Change in body composition | Change in neuromuscular function | Change in metabolic profile | Changes in muscle cross-sectional area

URL: http://ClinicalTrials.gov/show/NCT02248701

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

Study Designs: Allocation: Randomised | Endpoint Classification: Safety/Efficacy Study | Intervention Model: Parallel Assignment | Masking: Quadruple

(Participant, Care Provider, Investigator, Outcomes Assessor) | Primary Purpose: Treatment

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

Sponsor/Collaborators: University of Calgary | Hotchkiss Brain Institute, University of Calgary | AANS / CNS Section on Disorders of the Spine and Peripheral Nerves

Gender: All

Age: Child | Adult | Senior

Phases: Phase 3

Enrolment: 100

Funded By: Other

Study Types: Interventional

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

Other IDs: E-24927

First Received: September 2, 2014

Start Date: February 2013

Completion Date: June 2018

Last Updated: October 30, 2017

Last Verified: October 2017

Acronym: MAPS

Results First Received: No Study Results Posted

Primary Completion Date: June 2018

Outcome Measures: Change in ASIA motor score from baseline, ASIA sensory score; Proportion of patients achieving a one-grade improvement in ASIA impairment scale (AIS); Quality of life assessment with Short-Form-36 (SF-36) Functional outcome assessment with FIM & SCIM

URL: https://ClinicalTrials.gov/show/NCT02232165

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 Politicas 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: FHNP-CT001

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
Interventions:	Drug: Abobotulinumtoxin A | Drug: Abobotulinumtoxin A | Drug: Abobotulinumtoxin A Placebo | Drug: Abobotulinumtoxin A Placebo

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 catherizations. | 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:

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