

Current clinical drug trials for improving functional outcomes in spinal cord injury

(updated 4 March 2014)

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1. The **Rick Hansen Institute Canada Inc** is recruiting patients for a Phase III clinical trial to assess the efficacy of IV minocycline in improving neurological and functional outcome after acute non-penetrating traumatic spinal cord injury (SCI). The University of Calgary and Alberta Paraplegic foundation are listed as collaborators. The primary hypothesis is that motor recovery will be improved through intravenous administration of minocycline twice daily administered to subjects with acute traumatic non-penetrating cervical SCI starting within 12 hours of injury.

See detail regarding the clinical trial in table below.

2. **StemCells, Inc** are conducting a **Phase I/II** study of the safety and preliminary efficacy of intramedullary spinal cord transplantation of human neural stem cells (**HuCNS-SC®**) in subjects with thoracic (T2-T11) spinal cord trauma. The trial is currently underway in Zurich, Switzerland and the estimated study completion date is March 2016. The treatment has an excellent safety profile and encouraging results have been obtained from three patients with complete injury. The clinical protocol has been amended to include patients with the less severe, incomplete injuries.

See detail regarding the clinical trial in table below.

3. **StemCells, Inc** is also enrolling participants by invitation from the abovementioned Phase I/II study in a long-term follow-up study, which is due to be completed in December 2018.

See detail regarding the clinical trial in table below.

4. **Neuralstem Inc** is enrolling participants by invitation for a Phase 1 study of human spinal cord-derived neural stem cell (HSSC) transplantation for the treatment of chronic spinal cord injury. Delivery of NSI-566 neural stem cells into the spinal cord will be accomplished using well-established stereotactic injection procedures. This study is due to be completed in March 2016.

See detail regarding the clinical trial in table below.

5. The **Rehabilitation Institute of Chicago** is still recruiting participants for a Phase 1 study on monoaminergic modulation of motor function in subacute incomplete SCI. They hypothesise that administering the SSRI antidepressant drug, Lexapro, early following SCI may facilitate independent stepping ability and improve locomotor recovery if the drug treatment is combined with intensive stepping training. Treatment with Lexapro may help to strengthen remaining nerve connections along the spine, giving patients more muscle control during rehabilitation exercises.

See detail regarding the clinical trial in table below.

6. The **Rehabilitation Institute of Chicago** is also recruiting participants for a Phase 1 study on serotonergic modulation of motor function in subacute and chronic SCI. The investigators propose to study the effects of Lexapro on strength and walking ability following human motor incomplete SCI. Using detailed electrophysiological recordings, in addition to measuring biomechanics and behaviour, the investigators will investigate the effects of Lexapro on motor behaviours during static and dynamic conditions.

See detail regarding the clinical trial in table below.

7. **Acorda Therapeutics** is now enrolling participants by invitation for a Phase 2 double-blind, randomised, placebo-controlled study which was scheduled to open in March 2013. The study is designed to determine the safety, tolerability and potential activity of AC105, a proprietary magnesium formulation that was licensed by Acorda in 2011. In preclinical studies, administration of AC105 within four hours of injury resulted in improvement of locomotor function. Phase 1 trials were completed in healthy volunteers. The U.S. Food and Drug Administration (FDA) granted Fast Track designation on February 12, 2009 for AC105 to improve functional recovery following treatment of acute SCI patients.

See detail regarding the clinical trial in table below.

8. **Asubio Pharmaceuticals, Inc** are still recruiting for a multicentre, randomised, double-blind, placebo-controlled, parallel-group **Phase 2** trial to evaluate the efficacy, safety, and pharmacokinetics of the **SUN13837** injection in adult subjects with acute spinal cord injury.

See detail regarding the clinical trial in table below.

9. **Hospital Nacional de Paraplégicos de Toledo** (Spain) are still recruiting for a triple-blinded, randomised, placebo-controlled **Phase 3** trial to evaluate the efficacy and safety of one year treatment based on daily doses of exogenous growth hormone (GH) in patients with traumatic spinal cord injury.

See detail regarding the clinical trial in table below.

10. **AOSpine North America Research Network** is now recruiting for a multi-centre, randomised, placebo controlled, double-blinded, **Phase 2/3** trial of efficacy and safety of **Riluzole** in acute spinal cord injury. The aim of this study is to evaluate efficacy and safety of riluzole in improving neurological motor outcomes of patients with acute spinal cord injury at 6 months post injury.

See detail regarding the clinical trial in table below.

11. **Kessler Foundation** is recruiting participants for an interventional, double-blind **Phase 2** trial of dalfampridine treatment (previously approved by the FDA as a treatment to improve walking in people with Multiple Sclerosis) in combination with locomotor training in persons with chronic, motor incomplete SCI. They hypothesise that persons undergoing combination therapy with dalfampridine and locomotor training will show significantly greater improvements in walking speed and other measures of SCI function than those receiving locomotor training alone.

See detail regarding the clinical trial in table below.

1. Minocycline in Acute Spinal Cord Injury (MASC)

NCT 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: Both

Age Groups: Child|Adult|Senior

Phases: Phase 3

Enrollment: 248

Funded Bys: Other

Study Types: Interventional

Study Designs: Allocation: Randomized|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: June 26, 2013

Last Verified: June 2013

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>

2: Study of Human Central Nervous System Stem Cells (HuCNS-SC) in Patients With Thoracic Spinal Cord Injury

NCT Number: NCT01321333

Recruitment: Recruiting

Study Results: No Results Available

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

Interventions: Procedure: HuCNS-SC cells

Sponsor/Collaborators: StemCells, Inc.

Gender: Both

Age Groups: Adult

Phases: Phase 1|Phase 2

Enrollment: 12

Funded Bys: Industry

Study Types: Interventional

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

Other IDs: CL-N02-SC

First Received: March 21, 2011

Start Date: March 2011

Completion Date: March 2016

Last Updated: January 17, 2014

Last Verified: January, 2014

Results First Received: No Study Results Posted

Primary Completion Date: December 2015

Outcome Measures: Types and frequencies of adverse events and serious adverse events

URL: <http://ClinicalTrials.gov/show/NCT01321333>

3: Long-Term Follow-Up of Transplanted Human Central Nervous System Stem Cells (HuCNS-SC) in Spinal Cord Trauma Subjects

NCT Number: NCT01725880

Recruitment: Enrolling by invitation

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Other: Observation

Sponsor/Collaborators: StemCells, Inc.

Gender: Both

Age Groups: Adult

Phases:

Enrollment: 12

Funded Bys: Industry

Study Types: Observational

Study Designs: Observational Model: Cohort|Time Perspective: Prospective

Other IDs: CL-N03-SC|TpP_I_2012_002

First Received: November 9, 2012

Start Date: November 2012

Completion Date: March 2019

Last Updated: October 15, 2013

Last Verified: October 2013

Results First Received: No Study Results Posted

Primary Completion Date: December 2018

Outcome Measures: American Spinal Injury Association (ASIA) Impairment Scale Improvement

URL: <http://ClinicalTrials.gov/show/NCT01725880>

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

NCT Number: NCT01772810
Recruitment: Enrolling by invitation
Study Results: No Results Available
Conditions: Spinal Cord Injury (SCI)
Interventions: Device: Human spinal cord stem cells.
Sponsor/Collaborators: Neuralstem Inc.
Gender: Both
Age Groups: Adult
Phases: Phase 1
Enrollment: 8
Funded By: Industry
Study Types: Interventional

Study Designs: Endpoint Classification: Safety Study|Intervention Model: Single Group Assignment|Masking: Open Label|Primary Purpose: Treatment

Other IDs: NS2010-1
First Received: January 14, 2013
Start Date: February 2014
Completion Date: March 2016
Last Updated: January 3, 2014
Last Verified: January 2013
Acronym: SCI

Results First Received: No Study Results Posted

Primary Completion Date: February 2016

Outcome Measures: The primary objective of the study is to determine the safety of human spinal stem cell transplantation for the treatment of paralysis and related symptoms due to chronic spinal cord injury (SCI)|The secondary objective of the study is to evaluate the graft survival in the transplant site by MRI.

URL: <http://ClinicalTrials.gov/show/NCT01772810>

5: Monoaminergic Modulation of Motor Function in Subacute Incomplete Spinal Cord Injury (SCI)

NCT Number: NCT01753882

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Drug: Lexapro|Drug: Placebo

Sponsor/Collaborators: Rehabilitation Institute of Chicago

Gender: Both

Age Groups: Adult|Senior

Phases: Phase 1

Enrollment: 88

Funded Bys: Other

Study Types: Interventional

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

Other IDs: STU00056589

First Received: December 6, 2012

Start Date: February 2012

Last Updated: November 18, 2013

Last Verified: November 2013

Results First Received: No Study Results Posted

Primary Completion Date: July 2014

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>

6: Serotonergic Modulation of Motor Function in Subacute and Chronic SCI

NCT Number: NCT01788969
Recruitment: Recruiting
Study Results: No Results Available
Conditions: Spinal Cord Injury
Interventions: Drug: Lexapro|Drug: Placebo
Sponsor/Collaborators: Rehabilitation Institute of Chicago
Gender: Both
Age Groups: Adult
Phases: Phase 1
Enrollment: 120
Funded Bys: Other
Study Types: Interventional

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

Other IDs: STU00014259
First Received: February 7, 2013
Start Date: June 2005
Completion Date: July 2014
Last Updated: November 18, 2013
Last Verified: November 2013
Results First Received: No Study Results Posted
Primary Completion Date: July 2014

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/NCT01788969>

7. A Study of AC105 in Patients With Acute Traumatic Spinal Cord Injury

NCT Number: NCT01750684

Recruitment: Enrolling by invitation

Study Results: No Results Available

Conditions: Acute Spinal Cord Injury

Interventions: Drug: AC105|Other: Placebo

Sponsor/Collaborators: Acorda Therapeutics|DP Clinical, Inc.

Gender: Both

Age Groups: Adult

Phases: Phase 2

Enrollment: 40

Funded By: Industry|US Fed

Study Types: Interventional

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

Other IDs: ACPM-SI-1009

First Received: December 13, 2012

Start Date: July 2013

Completion Date: June 2015

Last Updated: November 14, 2013

Last Verified: November 2013

Acronym: AC105

Results First Received: No Study Results Posted

Primary Completion Date: June 2015

Outcome Measures: Safety and tolerability assessed by comparing adverse event (AE) data for patients administered a regimen of 6 intravenous doses of AC105 over 30 hours compared with patients administered the same regimen of placebo.|Pharmacokinetic (PK) parameters of AC105 using individual patient plasma concentration-time data

URL: <http://ClinicalTrials.gov/show/NCT01750684>

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

NCT Number:	NCT01502631
Recruitment:	Recruiting
Study Results:	No Results Available
Conditions:	Acute Spinal Cord Injury
Interventions:	Drug: SUN13837 injection Drug: Placebo
Sponsor/Collaborators:	Asubio Pharmaceuticals, Inc.
Gender:	Both
Age Groups:	Child Adult Senior
Phases:	Phase 2
Enrollment:	164
Funded Bys:	Industry
Study Types:	Interventional

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

Other IDs:	ASBI 603
First Received:	December 27, 2011
Start Date:	January 2012
Completion Date:	November 2014
Last Updated:	January 9, 2014
Last Verified:	January 2014
Results First Received:	No Study Results Posted
Primary Completion Date:	November 2014

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: <http://ClinicalTrials.gov/show/NCT01502631>

9: Efficacy and Safety of Growth Hormone Treatment in Spinal Cord Injury

NCT Number: NCT01329757

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Drug: GH|Drug: Placebo

Sponsor/Collaborators: Hospital Nacional de Paraplégicos de Toledo|Ministerio de Salud y Políticas Sociales (Ministry of Health)

Gender: Both

Age Groups: Adult|Senior

Phases: Phase 3

Enrollment: 76

Funded Bys: Other

Study Types: Interventional

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

Other IDs: FHNP-CT001

First Received: April 4, 2011

Start Date: April 2011

Completion Date: December 2014

Last Updated: November 19, 2012

Last Verified: November 2012

Acronym: GHSCI

Results First Received: No Study Results Posted

Primary Completion Date: December 2014

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>

10: 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

Gender: Both

Age Groups: Adult|Senior

Phases: Phase 2|Phase 3

Enrollment: 351

Funded Bys: Other|Industry

Study Types: Interventional

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

Other IDs: SPN-12-001

First Received: May 10, 2012

Start Date: August 2013

Completion Date: December 2015

Last Updated: November 26, 2013

Last Verified: November 2013

Acronym: RISCIS

Results First Received: No Study Results Posted

Primary Completion Date: October 2015

Outcome Measures: Change in ISNCSCI Total Motor Score between 180 days and baseline

URL: <http://ClinicalTrials.gov/show/NCT01597518>

Study 11: Combination Therapy With Dalfampridine and Locomotor Training for Chronic, Motor Incomplete Spinal Cord Injury

NCT Number: NCT01621113

Recruitment: Recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Drug: Dalfampridine|Drug: Placebo

Sponsor/Collaborators: Kessler Foundation|U.S. Department of Education|Acorda Therapeutics

Gender: Both

Age Groups: Adult|Senior

Phases: Phase 2

Enrollment: 46

Funded Bys: Other|U.S. Fed|Industry

Study Types: Interventional

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

Other IDs: D-732-12|H133N110020

First Received: June 12, 2012

Start Date: June 2012

Completion Date: October 2016

Last Updated: December 27, 2012

Last Verified: December 2012

Results First Received: No Study Results Posted

Primary Completion Date: October 2016

Outcome Measures: Change in 6-Minute Walk Test (6MWT) Distance at 10 Weeks|Change in 10-Meter Walk Test (10MWT) Speed at 10 Weeks|Change in Timed 25-foot walk (T25FW) Speed at 10 Weeks|Change in Walking Index for Spinal Cord Injury II (WISCI II) Scores at 10 Weeks|Change in Spinal Cord Injury Functional Ambulation Index (SCI-FAI) Scores at 10 Weeks|Changes on International Standards for Neurological Classification of Spinal Cord Injury at 10 Weeks|Change in Lower-Extremity Motor Scores (LEMS) at 10 Weeks|Change in Berg Balance Scale (BBS) Scores at 10 Weeks|Change in Modified Ashworth Scale (MAS) Scores at 10 Weeks|Change in Bowel Management Questionnaire Scores at 10 Weeks|Change in Bladder Management Questionnaire Scores at 10 Weeks|Change in Female Sexual Function Index (FSFI) Scores at 10 Weeks|Change in International Index of Erectile Function (IIEF) Scores at 10 Weeks|Changes in Pulmonary Function Tests at 10 Weeks|Changes in Autonomic Function at 10 Weeks|Changes on the International Spinal Cord Injury Pain Basic Data Set (ISCI-PDS:B) at 10 Weeks|Change in Spinal Cord

Independence Measure III (SCIM III) Scores at 10 Weeks|Change in Spinal Cord Injury-Functional Index (SCI-FI) Scores at 10 Weeks|Change in 12-Item Short Form Health Survey (SF-12) Scores at 10 Weeks|Change in Satisfaction with Life Scale (SWLS) Scores at 10 Weeks|Change in Craig Handicap Assessment and Reporting Technique (CHART) Scores at 10 Weeks|Change in Subject Global Impression (SGI) of Change at 10 Weeks|Change in Clinician Global Impression (CGI) of Change at 10 Weeks|Adverse Event Case Report Form|Side Effects Record

URL: <http://ClinicalTrials.gov/show/NCT01621113>