Current clinical drug trials for improving functional outcomes in spinal cord injury
(updated 6 June 2014)

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1. The Rick Hansen Institute Canada Inc is recruiting patients for a Phase II 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 2015. 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 has changed the recruitment status of their Phase 1 study of human spinal cord-derived neural stem cell (HSSC) transplantation for the treatment of chronic spinal cord injury from “enrolling by invitation” to “not yet recruiting”. 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 February 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 started in July 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) following a regimen of 6 intravenous doses over 30 hours in patients with acute non-penetrating traumatic spinal cord injury. 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.

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 Parapléjicos 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.

12. **BioAxone BioSciences Inc.** will be conducting a multicenter, randomized, double-blind, placebo-controlled **Phase IIb** study designed to evaluate the efficacy and safety of **Cethrin** as a treatment for acute cervical spinal cord injury. It appears that at this stage they are not recruiting participants, and their primary outcome measure will be an ASIA Upper Extremity Motor Score. Cethrin has been granted Fast Track status by the Food and Drug Administration (FDA), allowing for accelerated review in the United States. Cethrin is said to inactivate Rho by ADP ribosylation.

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 By: Other

Study Types: Intervventional

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: Active, not recruiting
Study Results: No Results Available
Interventions: Procedure: HuCNS-SC cells
Sponsor/Collaborators: StemCells, Inc.
Gender: Both
Age Groups: Adult
Phases: Phase 1, Phase 2
Enrollment: 12
Funded By: 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: December 2015
Last Updated: April 23, 2014
Last Verified: April, 2014
Results First Received: No Study Results Posted
Primary Completion Date: May 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 By: Industry
Study Types: Observational
Study Designs: Observational Model: Cohort/Time Perspective: Prospective
Other IDs: CL-N03-SCITpP_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: Not yet recruiting
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: Intervventional
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: May 2014
Completion Date: March 2016
Last Updated: April 24, 2014
Last Verified: April 2014
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 By:** 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:** April 23, 2014
- **Last Verified:** April 2014
- **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 By: 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: April 23, 2014
Last Verified: April 2014
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: May 29, 2014
Last Verified: May 2014
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 By: 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: March 3, 2014
Last Verified: March 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 Parapléjicos de Toledo|Ministerio de Salud y Politicas Sociales (Ministry of Health)

Gender: Both
Age Groups: Adult|Senior
Phases: Phase 3
Enrollment: 76
Funded By: 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: FHNPC-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: May 15, 2014
Last Verified: May 2014
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 By: 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
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 (ISCIPDS: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
Study 12: **Cethrin in Acute Cervical Spinal Cord Injury**

NCT Number: NCT02053883

Recruitment: Not yet recruiting

Study Results: No Results Available

Conditions: Spinal Cord Injury

Interventions: Drug: Cethrin (BA-210)|Drug: Placebo

Sponsor/Collaborators: BioAxone BioSciences, Inc.

Gender: Both

Age Groups: Adult

Phases: Phase 2

Enrollment:

Funded By: Industry

Study Types: Intervenational

Study Designs: Allocation: Randomized|Endpoint Classification: Safety/Efficacy

Study Intervention Model: Parallel Assignment|Primary Purpose: Treatment|Masking: Double-Blind

Other IDs: BA-210-201

First Received: January 31, 2014

Start Date:

Completion Date:

Last Updated: February 1, 2014

Last Verified: February 2014

Results First Received: No Study Results Posted

Primary Completion Date: July 2016

Outcome Measures: American Spinal Injury Association (ASIA) Upper Extremity Motor Score Recovery|ASIA Total Motor Score Recovery|ASIA Impairment Scale (AIS) Grade Recovery|Motor Neurological Level Recovery|ASIA Sensory Score Recovery|Spinal Cord Independence Measure (SCIM) III (Total Score, Self-Care Subscore)|Graded Redefined Assessment of Strength, Sensibility and Prehension (GRASSP)|Incidence of Adverse Events

URL: http://ClinicalTrials.gov/show/NCT02053883