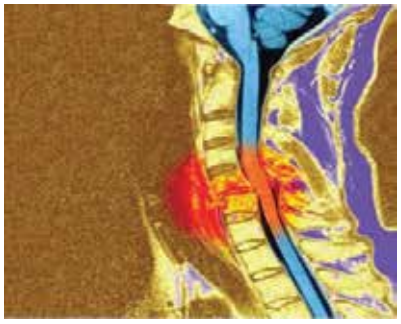
The Riluzole in Spinal Cord Injury Study

Currently recruiting

The Riluzole in Spinal Cord Injury Study (RISCIS) is principally sponsored by AOSpine North America with partnership and co-funding from: AOSpine International Spinal Cord Injury Knowledge Forum; North American Clinical Trials Network (NACTN); US Department of Defense (DOD); Ontario Neurotrauma Foundation; Rick Hansen Institute (RHI), and Christopher and Dana Reeve Foundation. RISCIS is a worldwide multicentre trial launched to evaluate efficacy and safety of Riluzole in improving neurological motor outcomes of patients with acute spinal cord injury at 6 months post injury.



Under the U of T Spine Program umbrella, the trial is launched and approved for data sharing agreement at three affiliated sites: Toronto Western Hospital (TWH); Sunnybrook Health Sciences Centre (SHSC); and St. Michael's Hospital (SMH). Eligibility is Age 18 to 75 years, Acute (< 14 days old) spinal cord injury of traumatic origin, Spinal cord injury at the neurologic level from C4 to C8, ASIA Impairment Scale level A, B or C, and no other life-threatening injury.

Principal Ivestigators:
Michael Fehlings (Lead), UHN-Toronto Western Hospital. michael.fehlings@uhn.cal
Albert Yee, Sunnybrook Health Sciences Centre. Albert.Yee@sunnybrook.ca
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Contact Research Coordinators:
TWH: Yuriy Petrenko. (416) 790-4535. Yuriy.Petrenko@uhn.ca
SHSC: Katrine Milner. (416) 505-7686. katrine.milner@sunnybrook.ca.
SMH: Kayee Tung. (416) 864-6060 Ext. 2713. TungK@smh.ca

For eligibility and inclusion criteria check
ClinicalTrials.gov Identifier: NCT01597518

Lumbar Spinal Stenosis Study

The trial has completed recruitment of 104 participants for this study. Follow-up assessments are 8 weeks, 3 months, 6 months, and 12 months with primary outcome in change in walking capacity measured at 6 months. The trial falls under the umbrella of the U of T Spine Program.

Contact Investigator: Carlo Ammendolia , Mount Sina Hospital. CAmmendolia@mtsinai.on.caok Health Sciences Centre. Arjun.-Sahgal@sunnybrook.ca

Update by the PI

We have completed the final 12 m follow-up assessment of our participants in our clinical trial.

At 8 weeks follow-up mean change from baseline in walking ability was +502 meters in the comprehensive group compared to 201m in the control group. At 12 m the mean improvement in walking ability was + 675 m in comprehensive group compared to 201 m in the control group. These are clinically important improvements in walking ability that were sustained at long term follow-up even after the termination of the active intervention. Clinically important improvements were also seen in the functional score of the Zurich Claudication Scale and the composite score of the symptom and functional scores of the Zurich Claudication Scale. We are currently assessing prognostic factors and co-interventions. We will be interested in seeing whether compliance to participants' respective program was factor in improved walking ability.

Carlo Ammendolia

The Epidemiology, Process and Outcomes of Spine Oncology (EPOSO)

Currently recruiting

The main purpose of this study is to utilize a comprehensive, prospective clinical database to collect patient, diagnostic and treatment variables along with disease specific and generic health related quality of life (HRQOL) data on consecutively treated patients with metastatic spine tumors. The objectives are to determine the validity and reliability of the Spine Cancer Outcomes Questionnaire (SCOQ) for use in the assessment of spine tumor outcomes, to determine if the Spine Instability Neoplastic Score (SINS) Classification is a valid tool for predicting the stability of spine in metastatic spine disease, and to determine the efficacy of surgery versus radiotherapy for the treatment of impending instability secondary to metastatic disease of the spine.

This is an international multi-centre trial spanning centres in Hungary, USA, and Canada including our affiliated hospitals SBHSC, and UHN-TWH.

Sponsored by: AOSpine International

Principal Ivestigators:
Arjun Sahgal, Odette Cancer Centre-Sunnybrook Health Sciences Centre. Arjun.Sahgal@sunnybrook.ca
Michael Fehlings, UHN-Toronto Western Hospital. michael.fehlings@uhn.ca

For eligibility and inclusion criteria check
ClinicalTrials.gov Identifier: NCT01825161

Update from the PI:

Recruitment is almost closed, following which, the Metastatic Tumor Research and Outcome Network (MTRON) will be initiated. MTRON will be an international multi-centre prospective registry for the management of metastatic spine tumors. It will be co-led internationally by Drs Arjun Sahgal (U of T) and Charles Fisher (UBC). Again SHSC and UHN-TWH will open MTRON having successfully been high accruing centres for EPOSO.

Arjun Sahgal

SC. 24 A Randomized Phase II/III Study Comparing Stereotactic Body Radiotherapy (SBRT) Versus Conventional Palliative Radiotherapy (CRT) for Patient with Spinal Metastases

Currently recruiting

SC.24 is a Phase II randomized trial that has been moved to a Phase III trial comparing stereotactic body radiotherapy (SBRT – 24Gy in 2 fractions, developed at the University of Toronto) to conventional radiation (20Gy in 5 fractions) for patients with intact painful spinal metastases.

This trial is open in 8 sites across Canada including our affiliated hospitals SHSC and UHN.

Sponsored by: Canadian Cancer Trials Group

For eligibility and inclusion criteria check
ClinicalTrials.gov Identifier: NCT02512965

Study Chair: Dr Arjun Sahgal, Odette Cancer Centre-Sunnybrook Health Sciences Centre. Arjun.Sahgal@sunnybrook.ca

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

Currently recruiting

This new and is a phase 2b/3, double-blind, randomized, placebo controlled, multicenter Study desinged to determine the efficacy and safety of VX-210 in subjects with Acute Traumatic Cervical Spinal Cord Injury. Secondary objectives include the specific evaluation of the effects of VX-210 on neurological recovery and daily function after spinal cord injuryut of 54 have been recruited across Canada.

Sponsored by: Vertex Pharmaceuticals Incorporated

Principal Investigator: Michael Fehlings, UHN-Toronto Western Hospital. michael.fehlings@uhn.ca

Contact:
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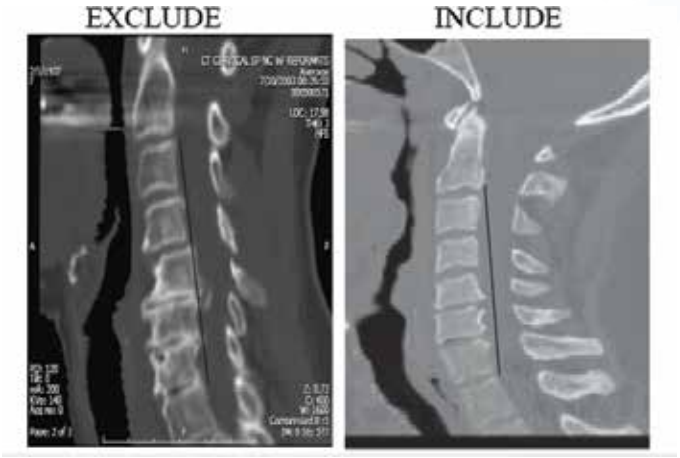
For eligibility and inclusion criteria check
ClinicalTrials.gov Identifier: NCT02669849

Cervical Spondylotic Myelopathy Surgical Trial

Currently recruiting

The purpose of the study is to determine the optimal surgical approach (ventral vs dorsal) for patients with multi-level cervical spondylotic myelopathy (CSM). There are no established guidelines for the management of patients with CSM, which represents the most common cause of spinal cord injury and dysfunction in the US and in the world.



This study aims to test the hypothesis that ventral surgery is associated with superior Short Form-36 physical component Score (SF-36 PCS) outcome at one year follow-up compared to dorsal approaches and that both ventral and dorsal surgery improve symptoms of spinal cord dysfunction measured using the modified Japanese Orthopedic Association Score (mJOA). A secondary hypothesis is that health resource utilization for ventral surgery, dorsal fusion, and laminoplasty surgery are different. A third hypothesis is that cervical sagittal balance post-operatively is a significant predictor of SF-36 PCS outcome.
ase of the spine.

This is an international Multi-Centre Trial being conducted in the United States and Canada including our affiliated hospital the UHN-TWH.

Sponsored by: Lahey Clinic, and Patient-Centered Outcomes Research Institute

Principal Ivestigators:
Michael Fehlings (Local), UHN-Toronto Western Hospital. michael.fehlings@uhn.ca
Zoher Ghogawala (Lead), Lahey Clinic, Inc. Zoher.ghogawala@lahey.org

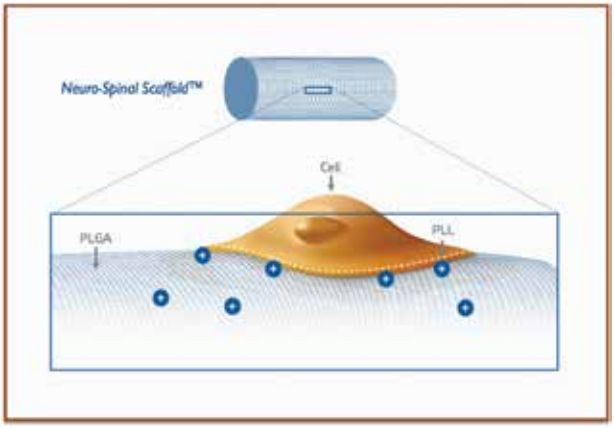
Contact: Yuriy Petrenko, 416-603-5285 . yuriy.petrenko@uhn.ca

For eligibility and inclusion criteria check

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

Currently recruiting

The purpose of this study is to evaluate whether the Scaffold is safe and demonstrates probable benefit for the treatment of complete T2-T12/L1 spinal cord injury . This is a Humanitarian Device Exemption (HDE) Probable Benefit Study to demonstrate safety and probable benefit in support of future studies and an HDE application with subsequent approval.



This is an international Multi-Centre Trial being conducted in the United States and Canada. The UHN- Toronto Western Hospital (PI Dr Michael Fehlings) has joind in July 2016 followed by ST. Michael's Hospital (PI Dr Howard Ginsberg).

Sponsored by: InVivo Therapeutics

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For eligibility and inclusion criteria check
ClinicalTrials.gov Identifier: NCT02138110

Special Inter-Professional Workshop on Primary Spine Tumors

In their capacity as Co-Directors of the U of T spine Program Drs. Michael Fehlings and Albert Yee and jointly with Drs. James Rutka (Chair, Department of Surgery) and Arjun Sahgal (Deputy Chief, Department of Radiation Oncology, Sunnybrook) are organizing a special workshop on Primary Spine Tumors on Saturday, September 23 2017.

The workshop is to provide the latest update on the surgical management of primary osseous spine tumors. Dr. Peter Varga from Budapest will speak on sacral chordoma and reconstruction techniques; Dr. Larry Rhines from MD Anderson on the role of plastics for complex spine surgery for mobile spine tumors; Dr Ziya Gokaslan from Brown university on en bloc surgery for mobile spine tumors; and Dr. Charles Fisher from Vancuver,UBC on the AOSpine guidelines for primary spinal tumors.

This half-day workshop is targeted towards staff spine surgeons in the GTA followed with discussions on improving the standardization for the surgical management of complex cases.

Combined Canadian Spinal Cord & Ontario Spinal Cord Injury Research Network Meeting

Our faculty and trainees are invited to attend the Combined Canadian Spinal Cord & Ontario Spinal Cord Injury Research Network Meeting being held on May 12-14, 2017 at the Toronto Marriott Downtown.

The ONF usually arranges a biennial OSCIRN meeting. Interestingly, however, this year's meeting will be in combination with the Canadian SCI (Repair, Rehabilitation and Reintegration) in order to bring together Basic and clinical researchers to promote forward and reverse bench-clinic translation. Our program is pleased to collaborate in this event and all our faculty members, committee members and their trainees are welcomed and encouraged to attend this meeting.