The MINOCYCLINE study (RHI 1005) is supported through a contribution from Health Canada and the Governments of Alberta and Ontario. The views expressed herein represent the views of the Rick Hansen Institute.

The Rick Hansen Institute is a Canadian-based not-for-profit organization with the goal of creating a world without paralysis after spinal cord injury. It works towards this goal by accelerating research and translating clinical findings into practical solutions to develop new treatments, improve health care outcomes, reduce long-term costs and improve the quality of life for those living with spinal cord injury. www.rickhanseninstitute.org

MINOCYCLINE IN ACUTE SPINAL CORD INJURY

PROJECT PURPOSE

The Minocycline in Acute Spinal Cord Injury Study is an investigator-initiated phase III multi-centre clinical trial for the use of minocycline as a neuro-protective therapeutic treatment for traumatic spinal cord injury (TSCI). A pilot study was conducted at the University of Calgary/Foothills Medical Centre led by Drs Steven Casha and John Hurlbert. The minocycline regimen established in the pilot study proved feasible, safe and was associated with a tendency towards improvement across several neurological and functional outcome measures. Although the study did not establish the efficacy of minocycline in SCI, the findings were encouraging and warranted further investigation in a multi-centre phase III trial.

The objective of this study is to assess the efficacy of intravenous (IV) minocycline in improving neurological and functional outcome after acute non-penetrating traumatic SCI.

STATUS

The study opened for enrollment in June 2013 with the first site initiated at the University of Calgary/Foothills Medical Centre. RHI continues to collaborate with other facilities to expand this trial internationally.

PRIMARY OBJECTIVES/HYPOTHESIS

IV minocycline administered twice daily for 7 days to subjects with acute traumatic non-penetrating cervical SCI starting within 12 hours of injury will improve motor recovery as assessed by the International Standards for Neurologic Classification of Spinal Cord Injury (ISNCSCI) neurological examination measured between three months and one year post-injury, as compared to placebo.

SECONDARY OBJECTIVES/HYPOTHESIS

IV minocycline administered twice daily for 7 days to subjects with acute cervical SCI starting within 12 hours of injury also results in improvement in functional outcome as assessed by Spinal Cord Independence Measure (SCIM) and Short Form (SF)-36, as compared to placebo.

The effect of minocycline on neurological and functional outcome after SCI is expected to be more pronounced in those subjects with motor incomplete SCI as compared to those with motor complete SCI.

PROJECT TEAM

Principal Investigators
Steve Casha, MD, PhD, FRCSC
John Hurlbert MD, PhD, FRCSC, FACS
University of Calgary

Current Study Sites
Calgary, London, Edmonton, Halifax, Ottawa, Brisbane (AUS)

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Clinicaltrials.gov: NCT01828203

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