

ISIS 18th Annual Scientific Meeting

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Abstract Title:

Comparative Study of Epidural Steroid Injection versus *mild*® Procedure in Patients Diagnosed with Symptomatic Moderate to Severe Lumbar Spinal Stenosis

Background:

Various minimally invasive and surgical options are used to perform lumbar decompressive procedures. The goal of the *mild* procedure is to effect a decompression with minimal surrounding tissue disruption. The standard medical therapy widely used to treat symptomatic lumbar spinal stenosis is a combination of pain medicine, epidural steroids (ESI) and/or physical therapy. Where conservative therapy fails, the common surgical procedures involve various techniques that range from an insertion of an interspinous decompression implant to moderate endoscopic or major open surgery. These all may result in various amounts of damage to large areas of tissue, muscle, ligaments and bone in the back. Recovery from the major surgical procedures is painful and can require several months of low activity and rest.

Objectives:

The purpose of this single-center, randomized, prospective, double-blind clinical study is to assess the clinical application and outcomes with *mild*® devices versus epidural steroid injection in patients with symptomatic moderate to severe lumbar spinal stenosis.

Methods:

Patients with symptomatic lumbar spinal stenosis who meet the study enrollment criteria are randomized to either ESI or the *mild*® procedure. Patients are treated with the *mild*® procedure under radiographic image guidance as described in the *mild*® product labeling, or with ESI. Neither the enrolling physician nor the subject is aware of the subject's ultimate treatment group. These patients are followed for a period of up to 6 months in order to assess patient outcomes. Complete enrollment will include 40 adult patients at one study center.

Documentation of concomitant and pain medication usage, neurological examination, Visual Analog Score (VAS), Quality of Life (SF-12), Oswestry Disability Index (ODI), and Zurich Claudication Questionnaire (ZCQ) are made during the scheduled screening/baseline physical examination prior to study treatment. Patient follow-up via telephone survey and office visits

include documentation of the same above measures and any medication changes. Device-related and significant adverse events are documented throughout the study period.

Results:

Enrollment is under way for this study, and is anticipated to be completed during the first half of 2010. The *mild* and traditional injection therapy groups will be analyzed separately for safety and effectiveness, and the two groups will be compared. Outcome measures to be evaluated include:

- Ability to perform treatments as planned free of technical complications
- Acceptable safety, consistent with other similar procedures
- Subject success, supported by procedure completion and effectiveness
- Changes in back pain as measured by a 10-point VAS and pain medication requirements
- Function as measured subjectively by the ODI, and ZCQ patient questionnaires
- Quality of Life Physical Component Score (PCS) as measured by the SF-12 short form survey
- Changes in Neurological status as determined through physical examination
- Changes in pain medication requirements

Discussion and Conclusion:

The Discussion will compare safety and effectiveness of the two study groups. The Conclusion will summarize and assess the study findings.