

Spinal Cord Stimulation for Chronic Intractable Pelvic Pain: A Comparison of Lead Placement Techniques – Pilot Study

We will compare a spinal cord stimulation system with dual lead placement at the T11-L1 level to sacral root stimulation by dual lead placement at the S2, S3 level using the retrograde technique.

We will use both implant techniques on all patients for the one week trial period. Each set of leads will be randomly activated for 3 days, separated by a one day break. At the end of this trial period the study doctors will decide which set of leads provided better pain relief by assessing outcome measures. The patient's permanent implant will be based on this decision. Only the patients obtaining an improvement of their pain of at least 50% will proceed to the 2nd phase of permanent implantation.

The study consists of 11 visits which take place over 6 months and include enrollment, lead placement, and follow-up.

Enrollment will remain open until a total of 10 implanted subjects are enrolled.

Inclusion criteria:

- Female over 18 years and pre-menopausal
- Chronic intractable pelvic pain which has failed appropriate conservative treatments (Appropriate conservative treatments include evidence based disease specific measures, such as hormonal management, non- narcotic and narcotic pain medication, surgery, physical therapy, psychotherapy, psychotropic medications)
- Willing to use an effective form of birth control for the duration of the study
- Sufficient cognition to understand function and operation of the device
- Psychological evaluation and clearance for implantation has been obtained.
- Able to provide written consent
- Willing to comply with study procedures

Exclusion Criteria:

- Major psychopathology
- Pregnancy
- High levels of dysfunctional behavior
- Stimulating or Sensing Devices (i.e.: Pacemakers)
- Serious drug habituation
- Contraindication to epidural lead placement and spinal cord stimulator implant (bleeding disorder, local or systemic infection)