Research Protocol

Project Title: InterStim Implantation Rate Following Percutaneous Nerve Evaluation With Fluoroscopy versus Without.

Principal Investigator: Sean Francis MD

Co-Investigators: Casey Kinman MD, Anubhav Agrawal MD, Kate Meriwether MD and Deslyn Hobson MD

Regulatory Coordinator: Sherree Goss RN, CCRC
University of Louisville, Dept of OB/GYN
Senior Research Nurse Coordinator/Research Manager for OB/GYN

Study Sites:
University of Louisville
University of Louisville HealthCare Outpatient Center (HCOC)
University of Louisville Hospital (ULH) Outpatient Surgery Center at HCOC
Jewish East Medical Center

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Protocol Summary/Purpose:

Sacral nerve stimulation (SNS) is a well-established treatment for refractory urinary urgency, frequency, retention and urge incontinence as well as fecal incontinence. Patients whose symptoms are refractory to more conservative therapies such as behavioral modification and/or medications are candidates for SNS. The InterStim system consists of a permanent tined lead and implantable pulse generator (IPG) or battery that delivers the sacral neuromodulation. This device is typically implanted after patients have a successful response to a trial of sacral neuromodulation with a temporary lead and external battery. The temporary lead placement is known as a Percutaneous Nerve Evaluation (PNE) and is typically done in as an outpatient procedure using local anesthetic. It is standard practice to use fluoroscopy intraoperatively to confirm correct placement of the permanent lead. Additionally, some physicians also use fluoroscopy to confirm correct placement of temporary lead during PNE while others place the lead based on anatomical landmarks and expected elicited responses for S3 stimulation.

We propose a randomized control trial comparing the rate of implantation of the InterStim device following (PNE) performed with or without fluoroscopic guidance.

Objective:

To compare rates of implantation of InterStim after percutaneous nerve evaluation (PNE) with and without fluoroscopic guidance.

Hypothesis:

There will not be a significant difference in the conversion rate in patients who receive PNE placed with fluoroscopy versus those who have PNE placed without fluoroscopy.

Introduction and Background:

Sacral nerve stimulation (SNS) is a well-established treatment for refractory urinary urgency, frequency, retention and urge incontinence as well as fecal incontinence. Patients whose symptoms are refractory to more conservative therapies such as behavioral modification and/or medications are candidates for SNS. Prior to placement of the implant, patients must first undergo percutaneous nerve evaluation (PNE) and test stimulation. During this outpatient procedure the patient is placed in the prone position and a needle is inserted into the S3 foramen bilaterally under local anesthetic. Correct placement of the needle is confirmed by eliciting the appropriate nerve stimulation responses, and in some cases by the use of fluoroscopy. When correct position is achieved, a temporary monopolar percutaneous lead is placed though each needle bilaterally and the needles removed. The leads are attached to an external stimulator that is worn for a period of 3 to 7 days. Patients keep voiding diaries during the test stimulation, and if they demonstrate a 50% or greater improvement in symptoms they are eligible for implantation of the permanent tined lead and pacemaker-like stimulator, or IPG. Most studies report a 40% to 50% implantation rate following PNE (1). While some practitioners reserve fluoroscopic guidance solely for placement of the permanent tined lead, some prefer to use fluoroscopy when placing the temporary lead during PNE as well.

Methods and Procedures:

Patients with refractory urinary or fecal urgency, frequency, or incontinence undergoing peripheral nerve evaluation prior to InterStim implantation will be recruited from the HCOC Urogynecology outpatient office and will be consented for participation in the study during their preoperative office visit or on the day of their procedure. We plan to enroll approximately 200 patients in the study. Subject participation will last approximately 3 months.

Patients will be randomized just before PNE by block randomization to either Group 1 or Group 2. .

Group 1: Fluoroscopy guided PNE
Group 2: PNE without fluoroscopic guidance

Patients randomized to Group 1 will have their PNE performed in the HCOC outpatient surgery center or at the Jewish East Medical Center under local anesthetic with fluoroscopic guidance. Fluoroscopy will be used to confirm correct needle and subsequent lead placement.

Patients randomized to Group 2 will also have the PNE performed in the HCOC outpatient surgery center or at the Jewish East Medical Center under local anesthetic but no fluoroscopy will be used. (This is our current practice for PNEs.)

As is standard practice following PNE, patients will complete a 3-7 day voiding diary pre and post procedure, and if a 50% or greater improvement in symptoms (number of voids, number of incontinent episodes, or less urgency) is documented they will be eligible for implantation of the tined lead and implantable pulse generator (IPG). We will then calculate implantation rates between the two groups.

Inclusion Criteria:

- Women age ≥18
- English speakers
- Patients with urinary urgency, frequency, or urge incontinence refractory to at least 1 other intervention who elect to undergo PNE

Exclusion Criteria:

- Patients in whom bilateral leads cannot be placed
- Pregnant women
- Prisoners
- Less than 18 years of age

Data Sources:

- Electronic medical record at HCOC will be used to collect data

Data Collection:

The following information will be collected from the electronic medical record and entered into an encrypted excel spreadsheet:

- Age
- Race
- BMI
- Preoperative diagnosis
- Previous treatments for urinary urgency, frequency, retention, and/or urinary or fecal incontinence
- Percent improvement in symptoms as determined by pre and post PNE voiding diaries
- Whether or not InterStim implanted within 3 months of PNE
- Date of PNE
- Date of implantation of InterStim (if applicable)
- PFDI-20, PISQ-12, PFIQ-7 quality of life surveys

Data Analysis and Statistical Methods:

The primary outcome will be the difference in the rate of implantation of InterStim after PNE in each group. Secondary outcomes will identify demographic and perioperative factors associated with increased rates of implantation. Demographic factors will include age, race, previous treatments, and percent improvement in symptoms as determined by pre and post PNE voiding diaries. Continuous variables will be compared using the non-paired T-test and categorical variables will be compared using the chi-squared test.

Data Handling/Storage

All identifying information and data collected during the course of this study will be kept secure and strictly confidential. All data will be stored electronically on a password protected, encrypted laptop in the possession of the study investigators. Data will NOT be stored on a 'cloud' type server per HIPAA regulations. If data is transported, it will be transported on an encrypted device such as an encrypted thumb drive, CD, or DVD.
Paper data collections forms will be utilized and data will be entered from the paper data form to an encrypted, password protected laptop or computer database. These data forms will be housed in a locked file cabinet in the fellow's office in OBGYN office in the Ambulatory Care Building with restricted access.

Potential Benefits:

We do not anticipate any direct benefits to our study participants.

Potential Risks:

Risks to PNE include bleeding, bruising, infection, and/or discomfort at the site of lead insertion as well as lead migration and a temporary tingling sensation like that of an electrical shock. Should the patient decide to proceed with implantation of the InterStim system the same risks apply as well as pain or discomfort at the implant site, device malfunction, or undesirable changes in urinary or bowel habits.

Additionally, this research study cannot practically be conducted without access and use of protected health information. Thus, the principle risk to patients involved in the study is a potential breach of confidentiality and misuse or exposure of this information. With this in mind, the investigators will conduct all research activities in such a way that maximizes data security and minimizes any risk of potential data breaches.

Protection of Human Subjects/Security of Data/Conduct of Study:

The investigators will take great care to protect and secure all study data collected for this study.

Risks for breaches of confidentiality will be minimized by entering data from the medical record or paper data collection forms to a password protected, encrypted computer database which will have limited access to the PI, Co-PIs and sub-investigators.

Personal identifiers (name, DOB, MR #) will be collected and retained in an encrypted excel spreadsheet (Key). However, all patient information will be completely de-identified by using a study code or number instead of identifiers for the purposes of data analysis and reporting.

Data will be de-identified as soon as is feasible without compromising the study. Data will be stored as an encrypted file on a password protected laptop computer or encrypted thumb drive. Data will NOT be stored on a 'cloud' type server per HIPAA regulations.

A de-identified, password protected, encrypted spread sheet will be provided to the statistician for statistical analysis. Statistical consultants will not be added to this study since they will only work with totally de-identified data and will never see actual images or medical records.

The protected health information gathered for this study will be destroyed as soon as is feasible and will not be reused or disclosed to any other person or entity, except as required by law.

The excel "key" spreadsheet listing Research ID #, name, DOB, and, MR# may be disclosed to staff at the HCOC so that they may upload the required research documents into the Allscripts electronic medical record. As soon as all data have been collected and there is no further need to return to a subject's medical record, the Excel key(s) linking name, DOB and MR # to research ID numbers will be destroyed.

The research personnel involved in this study Casey Kinman MD, Anubhav Agrawal MD, Sean Francis MD, Kate Meriwether MD, Deslyn Hobson and Sherree Goss RN, CCRC (regulatory only) are CITI and HIPAA trained. No additional personnel are involved at this time. If new research personnel are added to the study, an amendment will be submitted to and approved by the IRB before being allowed to participate in the study.

Adverse Event Reporting and Data Monitoring:

The research team will closely monitor data collection and assure confidentiality at every point during this study. The IRB and appropriate hospital research office will be notified immediately of any adverse events, including security breaches of the data, or UPIRTSOs, whether expected or unexpected.

References

1. Baxter, Chad, Kim, Ja-Hong: Contrasting the Percutaneous Nerve Evaluation Versus Staged Implantation in Sacral Neuromodulation. Curr Urol Rep. Sep 2010; 11(5): 310–314.