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Reducing radiation exposure during InterStim lead placement

Submission date
01/01/2017

Recruitment status
No longer recruiting

Registration date
10/01/2017

Overall study status
Completed

Last Edited
09/01/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When people have an overactive bladder or bowel incontinence they have problems with their bladder-storage function or with an inability to control bowel movements. This happens because there is muscle and nerve damage that is associated with things like aging or giving birth. An overactive bladder or bowel incontinence is usually treated with various behavioral techniques, such as exercises to train bladder or bowel training, and medication. If these treatments failed, then a treatment called nerve stimulation is often used. This procedure uses a thin wire placed close to the sacrum (tailbone) where it passes near the sacral nerves which carry signals to the bladder and muscles in the bowel. This procedure is often done with a trial of a temporary wire or as an advanced procedure in which the permanent electrode (conductor) is implanted. When the doctors perform the placement, they use an imaging tool called fluoroscopy that guides them while the stimulator wire is being placed. This is a type of medical imaging that shows an X-ray image on a monitor. During a fluoroscopy procedure, an X-ray beam is passed through the body. The image is transmitted to a monitor so the movement of an instrument through the body can be seen in detail. The use of x-rays carries a minor risk as it uses radiator. Ultrasound imaging (sonography) uses high-frequency sound waves. Because ultrasound images are captured in real-time, they can also show movement of the body's internal organs as well as blood flowing through the blood vessels. Unlike X-ray imaging, there is no ionizing radiation exposure associated with ultrasound imaging. The aim of this study is to look at the effectiveness of ultrasound imaging to implant the InterStim® neurostimulator (a nerve stimulation device).

Who can participate?
Adults with overactive bladder or bowel incontinence for whom standard treatments using exercises or medication have not worked.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups have the InterStim® neurostimulator device implanted in the sacral (tailbone) region using standard surgical techniques. Those in the first group have the device placed using fluoroscopy to guide placement of needles. This involves using a special x-ray machine to continually take pictures to show where the device should be placed. Those in the second group have the device placed

under ultrasound guidance. This involves using an ultrasound probe to show the area of interest on a monitor so the device can be correctly placed. The time taken to perform the procedures is recorded in both groups. At the start of the study, two weeks after surgery and two years later, participants in both groups complete questionnaires to assess their quality of life.

What are the possible benefits and risks of participating?
Participants in the ultrasound group may benefit from not being exposed to radiation from x-rays. There are no notable risks involved with participating.

Where is the study run from?
Metro Health Hospital (USA)

When is the study starting and how long is it expected to run for?
January 2015 to March 2018

Who is funding the study?
Metro Health Hospital (USA)

Who is the main contact?
Dr Jaschar Shakuri-Rad

Contact information

Type(s)
Scientific

Contact name
Dr Jaschar Shakuri-Rad

Contact details
Metro Health Hospital
5900 Byron Center Ave
Wyoming
United States of America
49519

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015-005

Study information

Scientific Title

Prospective randomized blinded study evaluating ultrasound versus fluoroscopy guided sacral InterStim® lead placement

Study objectives
Study aim:
The aim of the study is to compare outcomes of ultrasound versus fluoroscopically guided placement of sacral neuromodulation foramen needles.

Hypothesis:
Ultrasound guided placement will significantly reduce fluoroscopy time and produce equivalent patient symptom control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Metro Health Institutional Review Board, 03/03/2015, ref: 2015-005

Study design
Single-center blinded prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Overactive bladder, fecal incontinence

Interventions
Eligible participants are randomly assigned into either the fluoroscopy or ultrasound group. Randomization is performed using a computer generated randomization number which assigns each patient to either the fluoroscopy or ultrasound arm. The surgeon is blinded to randomization until just prior to the start of the procedure. Patients are blinded to randomization for the duration of the study.

Group 1: Participants undergo placement of InterStim neurostimulator foramen needles under fluoroscopic guidance. This involves placing the patient prone on the operating room table. After induction of anesthesia, a foramen needle is placed in the S3 foramen under live fluoroscopy (continuous x-ray). Once adequate position of the needle is confirmed, the

remainder of the procedure is performed per manufacturers recommendations (Please see www.medtronic.com for details).

Group 2: Participants undergo placement of InterStim neurostimulator foramen needles under ultrasound guidance. This involves placing the patient prone on the operating room table. After induction of anesthesia, a foramen needle is advanced into the S3 foramen under live ultrasound guidance. Once adequate position of the needle is confirmed, the remainder of the procedure is performed per manufacturers recommendations (please see www.medtronic.com for details).

Patients in both groups are then followed for two years under the current study protocol to determine long term outcomes.

Intervention Type
Device

Primary outcome measure
Overall surgery time is measured in seconds until the end of surgery

Secondary outcome measures
1. Number of skin punctures made during the surgical procedure
2. Quality of life is assessed using the following questionnaires at baseline, 4 weeks and 2 years:
2.1. The International Consultation on Incontinence Modular Questionnaire Overactive Bladder Symptoms Quality of Life (ICIQ-OABqol) for urinary symptoms
2.2. The Overactive Bladder Symptom Score (OABSS) for urinary symptoms
2.3. The Fecal Incontinence Quality of Life Scale (FIQL) for fecal incontinence

Overall study start date
20/01/2015

Completion date
03/03/2018

Eligibility

Key inclusion criteria
1. Diagnosis of overactive bladder, non-obstructive urinary retention, or fecal incontinence
2. Aged 18 years or older
3. Failure of previous conservative measures (i.e. behavior modification, biofeedback, pelvic floor training, at least one antimuscarinic or beta-agonist medication)
4. Medically fit to undergo proposed surgery
5. Patient able to consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Forty in total. Twenty in each arm.

Key exclusion criteria
1. Pregnant or planning on becoming pregnant
2. Severe or uncontrolled diabetes with peripheral nerve involvement
3. Knowledge of planned MRI or other procedures precluding implantation of device or need for removal
4. Severe BPH, prostate cancer, urethral stricture, or other mechanical obstruction
5. Active urinary tract, skin, or soft tissue infection

Date of first enrolment
04/03/2015

Date of final enrolment
03/03/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Metro Health Hospital
5900 Byron Center Ave
Wyoming
United States of America
49519

Sponsor information

Organisation
Metro Health Hospital

Sponsor details
5900 Byron Center Ave
Wyoming
United States of America
49519

Sponsor type
Hospital/treatment centre

Website
https://metrohealth.net/

ROR
https://ror.org/05515v279

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Metro Health Hospital

Results and Publications

Publication and dissemination plan
Plans to share and/or publish the results of this study through means of medical journals, posters, and scientific seminars.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
Planned publication of participant level data in a peer reviewed journal. Any additional information or data may be obtained after a formal request, which may have to be approved by our IRB department to ensure patient data protection as outlined in local, state, and national guidelines (HIPPA).

IPD sharing plan summary
Other