ISRCTN49693042 https://doi.org/10.1186/ISRCTN49693042

Stimulation of pudendal nerve for management of adult faecal incontinence using key hole surgery

Submission date 20/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/09/2016	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Faecal incontinence is the inability to control bowel movement, causing leakage of bowel contents from the back passage. It affects between 1-10% of adults, with 0.5-1% experiencing regular faecal incontinence episodes that affect their quality of life. It is more common in women and with advancing age. This study aims to manage and improve adult faecal incontinence by stimulating the pudendal nerve which controls the anal sphincter (back passage).

Who can participate?
Patients aged 18 or over who have experienced moderate to severe symptoms of faecal incontinence for more than 6 months and have not responded to conservative treatments

What does the study involve?
The procedure involves placing an electrode (thin wire) on to the pudendal nerve laparoscopically (keyhole surgery) under general anaesthesia. The wire is then connected to a small temporary battery taped to the lower back of the participant. Regular and gentle electrical pulses are passed along the wire from the battery to stimulate the nerve. During the test period of 2 weeks, the effectiveness of the procedure is measured using a specially designed questionnaire to assess faecal incontinence and quality of life.

What are the possible benefits and risks of participating?
This procedure aims to improve the symptoms of faecal incontinence and quality of life. It provides an alternative option for those patients who have failed to improve with conservative management and SNS (currently the preferred and approved surgical management of faecal incontinence). General complications include: heart and lung complications, temporary urinary retention (inability to pass urine), and deep vein thrombosis (blood clots). Complications related to the general anaesthetic include: wound infection and haematoma (collection of blood), haemorrhage (bleeding more than anticipated), failure of surgical equipment, and injury to other organs in the pelvis. Device-related complications include: failed implant procedure, wound infection, electrode (lead) dislodgement, lead migration/fragmentation (movement of lead), neurological pains in the legs, perineum and vagina, pain at the battery site due to non-infective

cause such as battery rotation, and lack or loss of effectiveness (reduced or lost response after operation).

Where is the study run from?
St James's University Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to September 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Laparoscopic trans-peritoneal pudendal nerve stimulation for management of faecal incontinence in adults

Study objectives
Pudendal nerve stimulation is effective for management of faecal incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC2 East of Scotland, 02/09/2016, ref: 16/ES/0088

Study design
Prospective UK single-site feasibility study

Primary study design
Interventional

Secondary study design
Feasibility study

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
Faecal incontinence

Interventions
The procedure involves placing an electrode (thin wire) on to the pudendal nerve laparoscopically (key hole surgery) under general anaesthesia. The wire is then connected to a small temporary battery taped to the lower back of participant. Regular and gentle electrical pulses are passed along the wire from the battery to stimulate the nerve. During the test period which is 2 weeks, the effectiveness of the procedure will be measured using a specially designed questionnaires to assess faecal incontinence and quality of life. All procedures will be carried out by the investigating team at St James's University Hospital.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Short-term safety and efficacy (Cleveland Clinic Incontinence Score (CCIS))
2. Impact on Quality of Life (QoL)
Measured prior to the surgery and 2 weeks after surgery.

Secondary outcome measures

1. Difference in the percentage of successes, as defined by the device in use and ≥ 50% improvement in the Cleveland Clinic Incontinence Score (CCIS), between pre-operative and 2 weeks post intervention
2. The safety of pudendal nerve stimulation as judged by explant rates and operative and post-operative complications
3. The effect on disease-specific QoL (Faecal Incontinence Quality of life Score (FiQol)) and overall QoL (SF-12 score)

Overall study start date
01/09/2016

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. Patients with moderate to severe faecal incontinence for more than 6 months and suffering ≥ two incontinence episodes per week
2. Patients should have had a trial of conservative management plus either be suitable for trial of sacral nerve stimulation (SNS) or have had unsuccessful outcome with trial of SNS
3. Patients willing to participate in this study
4. Age ≥18 years
5. Able to provide written and informed consent
6. Suitable candidate for surgery
7. Able and willing to comply with terms of the protocol including filling in questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Presence of anal sphincter augmentation device i.e. FENIX or ABS
2. Chronic gastro-intestinal motility disorder causing incontinence due to diarrhoea
3. Active anorectal sepsis or disease such as cancer
4. External rectal prolapse

5. Pregnancy
6. Suspected or known allergy to titanium
7. Multiply scarred abdomen precluding laparoscopic surgery

Date of first enrolment
01/09/2016

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Beckett Street
Leeds
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The result of this study will be published in scientific journals. This study is also part of MD (Doctor of Medicine) degree project.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No