

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

<b>Submission date</b> 20/04/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2016	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Mr Ibrahim Eltilib  
i.eltilib@nhs.net

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Sushil Maslekar

**Contact details**  
Ground Floor, Lincoln Wing  
St James's University Hospital  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF  
+44 (0)113 243 3144  
sushil.maslekar@nhs.net

## 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  $\geq 50\%$  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  $\geq$  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  $\geq 18$  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

United Kingdom

LS9 7TF

## **Sponsor information**

**Organisation**

University of Leeds (UK)

**Sponsor details**

Faculty Research Ethics and Governance Administrator

Faculty Research Office, Room 10.110, Level 10

Worsley Building, Clarendon Way

Leeds

England

United Kingdom

LS2 9JT

+44 (0)113 343 7587

[governance-ethics@leeds.ac.uk](mailto:governance-ethics@leeds.ac.uk)

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No