# The effect of sacral nerve stimulation on the treatment of patients with constipation resulting from difficulty in evacuating the rectum

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/08/2009		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/07/2011	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
20/05/2014	Digestive System			

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

**Prof Norman Williams** 

#### Contact details

Centre for Academic Surgery The Royal London Hospital Whitechapel Road London United Kingdom E1 1BB

## Additional identifiers

#### Protocol serial number

LREC number 06/Q0601/46, protocol dated 25/05/06 v1

# Study information

Scientific Title

Prospective randomised double-blind placebo-controlled crossover study of sacral nerve stimulation in patients with severe rectal evacuatory dysfunction and rectal hyposensitivity

#### **Study objectives**

Patients with constipation secondary to a rectal evacuatory disorder and rectal hyposensation will derive symptomatic improvement, with normalisation of rectal sensory thresholds to balloon distension, following sacral nerve stimulation.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Redbridge and Waltham Forest Local Research Ethics Committee approved on 14th August 2006 (ref: 06/Q0601/46)

#### Study design

Single centre randomised placebo-controlled double-blind crossover pilot study

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Constipation

#### **Interventions**

- 1. Anorectal physiology: this will take 30 minutes; patients selected for the study will be required to have full anorectal physiology investigations. This will consist of anal manometry, rectal sensory thresholds, pudendal nerve stimulation, endoanal ultrasound, defaecating proctogram and colonic transit study.
- 2. Implantation of the temporary sacral nerve stimulation wire this will take up to 60 minutes and can be done under local or general anaesthetic depending on patient choice. Throughout the procedure an image intensifier will be used intermittently to take x-rays, for a total of 2 3 minutes.
- 3. Rectal sensory thresholds this will take up to 5 minutes; subjects will have rectal sensory thresholds to balloon distension after two weeks, at the crossover period, and at the end of the trial at 4 weeks. This consists of a balloon on the end of a catheter which will be placed into the rectum through the anus. The balloon will be inflated with air and note will be made of the volume required before the subject has the first constant sensation (FCS), a sustained desire to defaecate (DDV) and the maximum volume they can tolerate (MTV).
- 4. Questionnaires related to quality of life (36-item short form health survey [SF36], Gaol), symptom scores (Wexner constipation scores) will be completed at the end of two weeks and then again at the end of 4 weeks

Intervention is sacral nerve stimulation, each patient has this for 4 weeks in total 2 with stimulation off (ie placebo and therefore the control), 2 weeks with the stimulation on. Neither investigator or patient knows which arm of the trial they are in. The blinding is removed at the end of the 4 weeks.

Contact Details for Patient Information Material: Chetan Bhan Specialist Registrar Academic Surgical Unit The Royal London Hospital London E1 1BB

#### Intervention Type

Other

#### **Phase**

Not Applicable

#### Primary outcome(s)

- 1. Normalisation of rectal sensory thresholds to balloon distension (first constant sensation, defaecatory desire volume, maximum tolerable volume)
- 2. Improvement in Cleveland Clinic Constipation scores
- 3. Increase in percentage of complete bowel movements from the bowel diaries

Measured at baseline then after two weeks and then after 4 weeks.

#### Key secondary outcome(s))

Improvements in the following criteria during the stimulation period:

- 1. Quality of life using validated methods of assessing health related quality of life (SF36) and gastrointestinal related quality of life (GIQoL)
- 2. Data from bowel diaries

Measured at baseline then after two weeks and then after 4 weeks.

#### Completion date

01/08/2010

## Eligibility

#### Key inclusion criteria

- 1. Patients aged 18 65 years, either sex
- 2. Incomplete and/or assisted evacuation
- 3. Idiopathic (no rectal surgery, no spinal and overt neurological history)
- 4. Failed maximal conventional therapy
- 5. Normal colonic transit and rectal diameter
- No significant mechanical obstructive abnormality on proctography
- 7. Unable to evacuate greater than 60% contrast in 3 minutes
- 8. Rectal hyposensation (based 2/3 abnormal values of first constant sensation [FCS], defecatory desire [DDV] and maximum tolerable volume [MTV] to balloon distension)

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Inability to provide informed consent
- 2. Severe concomitant medical conditions precluding randomisation to operative treatment
- 3. Neurological diseases such as diabetic neuropathy, multiple sclerosis and parkinson's disease
- 4. Other medical conditions precluding stimulation: e.g. bleeding disorders, certain cardiac pacemakers
- 5. Congenital anorectal anomalies or absence of native rectum due to surgery
- 6. Present evidence of external full thickness rectal prolapse
- 7. Previous rectal surgery (rectopexy/resection) done less than 12 months ago (24 months for cancer)
- 8. Stoma in situ
- 9. Chronic bowel disease such as inflammatory bowel disease, chronic uncontrolled diarrhoea
- 10. Anatomical limitations that would prevent successful placement of electrodes
- 11. Pregnancy or intention to become pregnant
- 12. Previous experience of sacral nerve stimulation (SNS)

#### Date of first enrolment

14/08/2006

#### Date of final enrolment

01/08/2010

## Locations

#### Countries of recruitment

United Kingdom

England

#### Study participating centre Centre for Academic Surgery

London United Kingdom E1 1BB

## Sponsor information

#### Organisation

Queen Mary, University of London (UK)

#### **ROR**

https://ror.org/026zzn846

# Funder(s)

#### Funder type

University/education

#### Funder Name

Barts and the London School of Medicine and Dentistry, Queen Mary University of London (UK) - Colorectal Development Unit, Academic Surgical Unit

## **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created Date adde	d Peer reviewed	? Patient-facing?
Results article	results	01/04/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes