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

Submission date	Recruitment status	[_] Prospectively registered
14/08/2009	No longer recruiting	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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 found in the interventions field below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
14/08/2006

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
6. 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre
Centre for Academic Surgery
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Queen Mary, University of London (UK)

Sponsor details
c/o Gerry Leonard
Queen Mary's Innovation Centre
Barts and the London School of Medicine and Dentistry
Joint Research and Development Office
Lower Ground Floor
5 Walden Street
Whitechapel
London
United Kingdom
E1 2EF

Sponsor type
Government

Website
http://www.smd.qmul.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2012		Yes	No