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CONtrol of Faecal Incontinence using Distal NeuromodulaTion

Submission date
18/07/2011

Recruitment status
No longer recruiting

Registration date
16/08/2011

Overall study status
Completed

Last Edited
02/10/2015

Condition category
Signs and Symptoms

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Faecal incontinence occurs when a person passes faeces (stools) without the usual control. It is a distressing condition that is actually very common although under-reported because of embarrassment. Milder symptoms may be managed by treatments such as dietary change, drugs and bowel retraining, but many patients still resort to surgery to improve symptoms. Although several operations exist to treat incontinence, it is now clear that these often have poor results. Two relatively new treatments called sacral nerve stimulation (SNS) and percutaneous tibial nerve stimulation (PTNS) involve sending pulses of electricity to the nerves controlling the bowel and muscles of the anus (anal sphincter). SNS does this by inserting electrodes in the lower back just above the tailbone and connecting them to an implanted electrical stimulator which is buried in the buttock and acts a bit like a heart pacemaker. In the last 10 years, SNS has been shown to be successful for faecal incontinence, achieving some improvement in at least three quarters of patients. In Europe, this procedure is fast becoming first treatment offered when non-surgical treatments fail. Nevertheless, SNS is not a miracle cure for all, requiring two operations, with potential complications and expensive equipment. PTNS is a simpler method in which a nerve is electrically stimulated under the skin by a very small needle at the ankle (a bit like acupuncture). This sends signals back to the spine region to try and achieve the same effect as SNS. Early results of PTNS suggest that it may be as good as SNS. If this is true, this is very important because it is much less invasive and considerably cheaper than SNS. The aim of this study is to determine the effectiveness of PTNS in the treatment of patients with faecal incontinence.

Who can participate?
Patients over the age of 18 who have faecal incontinence symptoms sufficiently severe to receive the treatment being studied. Patients who have suffered anal sphincter injury are also invited to participate as well as patients who have failed appropriate conservative therapies are also allowed to participate.

What does the study involve?
Participants will be randomly allocated to undergo either treatment with PTNS or have ‘fake’

stimulation (placebo). Treatment will involve attending the hospital or surgery for a 30-minute treatment each week for 12 weeks, as well as an appointment before the treatment commences to discuss the therapy, and an appointment afterwards to evaluate the success of the therapy.

What are the possible benefits and risks of participating?
This treatment may be successful at treating your incontinence problem. There are no serious side effects to the treatment.

Where is the study run from?
The study will take place primarily at the Royal London Hospital and 15 other centres in the UK.

When is study starting and how long is it expected to run for?
The study will commence in October 2011 and will last for 2 years. Each patient will only be involved for 4 months.

Who is funding the study?
The study is being funded by the National Institute for Health Research, which is a government funding body for the NHS.

Who is the main contact?
Miss Emma Horrocks (Academic Clinical Fellow)
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Contact information

Type(s)
Scientific

Contact name
Ms Emma Horrocks

Contact details
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Additional identifiers

Protocol serial number
HTA 09/104/16

Study information

Scientific Title
A pragmatic randomised double blind placebo-controlled trial of percutaneous tibial nerve stimulation in patients with faecal incontinence

Acronym
CONFIDeNT

Study objectives
To determine the effectiveness of percutaneous tibial nerve stimulation (PTNS) versus sham electrical stimulation on faecal incontinence (FI), based on:
1. Reductions in weekly FI episodes (primary outcome) and
2. Improvements in validated incontinence scores, patient-centered FI-related symptoms and disease-specific and generic quality of life measures (secondary outcomes)

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/0910416
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/54936/PRO-09-104-16.pdf

On 19/04/2012 the following changes were made to the trial record:
1. The overall trial start date was changed from 01/09/2011 to 01/02/2012.
2. The overall trial end date was changed from 01/12/2013 to 01/02/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City and East approved in June 2010, ref: 10/H0703/25 ; amendment 1 approved on 19/10/2010 and amendment 2 approved on 06/06/2011 and amendment 3 approved on 05/01/2012.

Study design
Multi-centre double-blinded placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Faecal incontinence

Interventions
Current interventions as of 19/04/2012:
Participants from up to 20 UK centres providing specialist nurse-led treatment for pelvic floor disorders will be randomised by a computer-based tool to receive PTNS or sham needle insertion and electrical stimulation. All participants follow an assessment period and 3-month treatment protocol of one 30-min session per week. Follow up will be at week 14.

Previous interventions:
Active Treatment Arm: Patients will receive PTNS using the recommended standard of 12 weekly 30 minute outpatient stimulations using the Urgent® PC Neuromodulation System (Uroplasty Ltd., Manchester, UK). Follow up will be at week 14.

Sham Stimulation Arm: The sham arm will use a modification of that used in the pivotal level I trial of Peters et al. in overactive bladder syndrome and previously validated by this group. This will involve using TENS as the placebo.

In both arms of the trial, the Urgent® PC Neuromodulation System and TENS machine are set up on all patients, but only one machine is turned on, depending on the arm of the trial. The legs are also shielded from the patients view, thus the patients remain blinded to the treatment. Each patient will undergo 12 weekly treatments for 30 minutes each. Follow up is at week 14.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measure(s) as of 19/04/2012:
The primary outcome is the proportion of patients achieving ≥ 50% reduction in faecal incontinence episodes per week.

Previous primary outcome measure(s):
Change in weekly FI episodes expressed as proportion of patients achieving more than or equal to 50% reduction in FI episodes per week.

Key secondary outcome(s))
Current secondary outcome measure(s) as of 19/04/2012:
1. Percentage change in episodes of faecal incontinence per week
2. Numeric continuous change in episodes of faecal incontinence per week
3. Cleveland Clinic Faecal Incontinence Score
4. Patient Centred Outcomes Form
5. Likert scale of patients' global impression of success
6. Disease-specific and generic quality of life measures (EQ-5D Health Questionnaire, SF-36, GI Quality of Life Index, Quality of Life Scale for Faecal Incontinence)
7. Short urinary symptom assessment by interview before and after the intervention.

Previous secondary outcome measure(s):
1. Percentage change FI episodes per week
2. Numeric continuous change in FI episodes per week
3. Validated incontinence scores
4. Patient-centred FI-related symptoms
5. Likert scale of patients global impression of success
6. Disease specific and generic quality of life measures
7. Short urinary symptom assessment
All measurements will be taken prior to commencement of the PTNS treatment and on the visit following the final treatment.

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/04/2012:
Participants aged more than 18 years with faecal incontinence who have failed conservative treatments and whose symptoms are sufficiently severe to merit further intervention, as determined by the Principal Investigator at each centre.

Previous inclusion criteria:
1. All patients over the age of 18 years, who have faecal incontinence symptoms sufficiently severe to warrant intervention
2. Who have failed appropriate conservative therapies
It is expected that many patients will have had National Institute for Health and Clinical Excellence (NICE)-recommended appropriate specialist investigations including structural and functional anorectal assessment although these are not mandatory. Anal sphincter injury is not a contra-indication.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 19/04/2012:
1. Inability to provide informed consent for the research study
2. Inability to fill in the detailed bowel diaries required for outcome assessments
3. Neurological diseases, such as diabetic neuropathy, multiple sclerosis, and Parkinson's disease (any participant with painful peripheral neuropathy)
4. Anatomical limitations that would prevent successful placement of needle electrode
5. Other medical conditions precluding stimulation - e.g., bleeding disorders, certain cardiac pacemakers, peripheral vascular disease or ulcer, lower leg cellulitis
6. Congenital anorectal anomalies or absence of native rectum due to surgery
7. A cloacal defect
8. Present evidence of external full thickness rectal prolapse
9. Previous rectal surgery (rectopexy / resection) done <12 months ago (24 months for cancer)
10. Stoma in situ
11. Chronic bowel diseases such as inflammatory bowel disease leading to chronic uncontrolled

diarrhoea
12. Pregnancy or intention to become pregnant
13. Previous experience of sacral nerve stimulation or PTNS

Previous exclusion criteria:
1. Inability to provide informed consent for the research study
2. Inability to fill in the detailed bowel diaries required for outcome assessments (this will exclude patients who do not speak / read English)
3. Neurological diseases, such as diabetic neuropathy, multiple sclerosis and Parkinson's disease (any patient with painful peripheral neuropathy)
4. Anatomical limitations that would prevent successful placement of needle electrode
5. Other medical conditions precluding stimulation: e.g. bleeding disorders, certain cardiac pacemakers, peripheral vascular disease
6. Congenital anorectal anomalies or absence of native rectum due to surgery
7. Present evidence of external full thickness rectal prolapse
8. Previous rectal surgery (rectopexy/resection) done < 12 months ago (24 months for cancer)
9. Stoma in situ
10. Chronic bowel diseases such as inflammatory bowel disease leading to chronic uncontrolled diarrhoea
11. Pregnancy or intention to become pregnant
12. Previous experience of SNS or PTNS

Date of first enrolment
01/02/2012

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Mary, University of London
London
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Sponsor information

Organisation
Queen Mary, University of London (UK)

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) (09/104/16)

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 added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2015		Yes	No
Results article	results	24/10/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes