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Sacral nerve stimulation or anal bulking therapy for faecal incontinence - a comparative study

Submission date
05/12/2012

Recruitment status
No longer recruiting

Registration date
10/01/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Faecal incontinence is a common disease with considerable reduction of quality of life. Sacral nerve stimulation (SNS) and anal bulking therapy (ABT) are two treatments that have been developed during the last 10 years and are now frequently used. No proper comparison has been made between the two. The aim of this study is to compares the two treatments.

Who can participate?
Adult persons with faecal incontinence. The person fills out an incontinence diary during 3 weeks. A minimum of two episodes of faecal incontinence per week is required for participation. People with specific concurrent diseases (eg previous rectal resection, inflammatory bowel disease) cannot participate.

What does the study involve?
Participants are randomly allocated to one of two treatments (SNS or ABT). After the treatment (surgery) the patients are followed for one year. During this time they fill out incontinence diaries and a questionnaire that evaluates Quality of Life. Minor or major adverse events are recorded.

What are the possible benefits and risks of participating?
Both treatments are part of regular health care and the risks are minor. The aim of the study is just the comparison of two treatment. There is no actual benefit for the patient. He/she gets a treatment for faecal incontinence.

Where is the study run from?
Gothenburg and Uppsala, Sweden. Hopefully one or two additional centres in Sweden and/or Norway will take part.

When is the study starting and how long is it expected to run for?
The study will start during Spring 2013 and is scheduled to end in 2 to 3 years.

Who is funding the study?
HTA-center, Gothenburg and Sahgrenska University Hospital (Sweden)

Who is the main contact?
Dr Lars Börjesson
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Contact information

Type(s)
Scientific

Contact name
Dr Lars Börjesson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Sacral nerve stimulation vs anal bulking for faecal incontinence - a randomised controlled trial

Study objectives
There is a difference in efficency between the treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gothenburg University Research Ethics Committee, 04 December 2011, ref: 858-11

Study design
Multicenter interventional randomised controlled trial

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 below to request a patient information sheet [Swedish]

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

Interventions
Two interventional arms:
1. Sacral nerve stimulation
2. Anal bulking therapy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Responding (> 50% reduction of the number of fecal incontinence episodes compared to baseline) proportion after one year after randomisation.

Secondary outcome measures
1. Change in number of faecal incontinence episodes
2. Change in deferring time
3. Change in incontinence score
4. Change in Quality of Life
5. Adverse events

Overall study start date
01/03/2013

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Patients with fecal incontinence with > or = 2 episodes of fecal incontinence/week.
2. > 18 years
3. Insufficient effect of conservative treatment (physiotherphy, diet, drugs).

4. At least one year duration of symptoms
5. At least one year after vaginal delivery
6. Ability to confirm informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Complete external sphincter defect (at least 90 degrees, whole length of the anal canal evaluated by physical examination of ultrasound).
2. Ongoing anorectal infection
3. Active inflammatory bowel disease
4. Anorectal implant.
5. Anorectal surgery within the last 12 months.
6. Mucosal prolaps (gr 3-4)
7. Rectal prolaps
8. Ongoing malignant disease
9. Ongoing immunosuppressive treatment
10. Treatment with warfarin
11. Rectal anastomosis
12. Neurologic disease (MS, ALS, Myelomeningocele etc.)
13. Previous pelvic radiotherphy
14. Ongoing anorectal pain
15. Included in other RCT
16. Pregnancy
17. Previously treated with any of the two alternatives in the study
18. Concurrent condition or disease that makes the person unsutable for the study according clinical jugement of the investigator (eg not likely to follow the study protocol).

Date of first enrolment
01/03/2013

Date of final enrolment
01/03/2015

Locations

Countries of recruitment

Sweden

Study participating centre
Sahlgrenska University Hospital
Gothenburg
Sweden
416 85

Sponsor information

Organisation
Sahlgrenska University Hospital (Sweden)

Sponsor details
Health Technology Assessment Center
Gothenburg
Sweden
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hta-centrum@vgregion.se

Sponsor type
Hospital/treatment centre

Website
http://www.sahlgrenska.se/hta-centrum

ROR
https://ror.org/04vgqjj36

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sahgrenska University Hospital (Sweden)

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