

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

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| Submission date 05/12/2012 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 10/01/2013 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 25/06/2020 | Condition category Digestive System | <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 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 compare 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 Sahlgrenska 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

Contact details
Sahlgrenska University Hospital
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416 85

Additional identifiers

Protocol serial number
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 efficiency 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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)

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

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 (physiotherapy, 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 radiotherapy
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 unsuitable for the study according clinical judgement 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)

ROR

<https://ror.org/04vgqjj36>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sahgreiska University Hospital (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration