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SaFaRI: Sacral nerve stimulation versus the FENIX TM magnetic sphincter augmentation for adult faecal incontinence: a randomised Investigation

Submission date
13/06/2014

Recruitment status
No longer recruiting

Registration date
17/06/2014

Overall study status
Completed

Last Edited
08/11/2022

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 (FI) affects between 5% and 10% of the adult population. It is more common in females and among older people, and is the second most common cause of admission to a nursing home. It affects a persons social, physical, and mental well-being and it is a substantial and increasing burden on NHS health resources. The purpose of the SaFaRI study is to look at two different surgical treatments for those suffering from Faecal Incontinence (FI): surgery to implant the FENIX TM Magnetic Sphincter Augmentation (MSA), which is a string of magnetic beads implanted around the muscle that controls the bowel (anal sphincter), and surgery for Sacral Nerve Stimulation (SNS), which involves implanting an electrode and battery to stimulate the nerves that control bowel continence. Surgery for SNS implants is the current preferred treatment for FI and is approved by the National Institute for Health and Clinical Excellence (NICE). The SaFaRI study has been designed to find out how well the FENIX TM MSA implant helps to control FI in the short-term and to see how much either surgical option improves the day-to-day life and overall well-being of FI sufferers. It will also look at the cost-effectiveness of each procedure for the NHS.

Who can participate?
Participants that suffer from moderate to severe FI symptoms (2 or more incontinent episodes per week) and have done so for more than 6 months and whos condition has not improved with other treatments.

What are the possible benefits and risks of participating?
The information gained from the study will be helpful in guiding surgeons as to the best approach for the surgical treatment of FI, which will benefit other sufferers with this condition.

Where is the study run from?
The study will be co-ordinated by the Clinical Trials Research Unit at the University of Leeds and will run in approximately 20 hospitals across the UK.

When is study starting and how long is it expected to run for?
Recruitment is anticipated to start in January 2015 and will last for 36 months.

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/35/07

Study information

Scientific Title
Safari: Sacral nerve stimulation versus the FENIX TM magnetic sphincter augmentation for adult faecal incontinence: a prospective, UK multi-site, parallel-group, randomised clinical study investigating the safety and efficacy of the FENIX TM magnetic sphincter augmentation (MSA) compared to sacral nerve stimulation (SNS) for adult FI.

Acronym
SaFaRI

Study objectives
The SaFaRI study aims to evaluate the safety and efficacy of the FENIX TM MSA implants compared to SNS implants for the treatment of moderate to severe faecal incontinence in adults. The study will also compare the two types of surgery in terms of quality of life for patients and cost-effectiveness.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/123507

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber Leeds West, submitted 02/04/2014, ref. 14/YH/0128

Study design
Prospective UK multisite, parallel-group, randomised clinical study investigating the safety and efficacy of FENIX TM MSA in adult FI resistant to conservative therapies compared to SNS

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

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

Interventions
SNS this is a two-stage procedure whereby a temporary percutaneous electrode is used to stimulate the sacral nerves for a period of two weeks, after which the effect on continence is assessed and the electrode removed. If the response is positive (≥ 50% improvement in continence episodes), a permanent electrode and battery (Interstim II®) are implanted. Both temporary and permanent SNS are performed as day-case procedures.

FENIX TM MSA implantation is a minimally invasive surgical procedure whereby the FENIX TM MSA device is implanted, through a perineal incision, around the anal sphincter complex under radiological control. It typically involves a hospital stay of 1-3 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in the percentage of successes, as defined by the device in situ and ≥ 50% improvement in the CCIS (Cleveland Clinic Incontinence Score) between the two treatments at 18 months post-randomisation

Secondary outcome measures
1. Safety of FENIX TM MSA or SNS, as judged by explant rates and operative (including those occurring during theatre-time and post-surgery stay) and post-operative complications (up to and including 12 months from the date of the last study surgery)
2. Change in generic and disease-specific QoL from baseline, as measured by CCIS (Cleveland Clinic Incontinence Score), OD-score (Obstructed Defecation Score), FiQOL (Faecal Incontinence Quality of Life), EQ-5DTM and SF12® at 6, 12 and 18 months post-randomisation
3. Cost-effectiveness, using QALY outcome measures, assessed by EQ-5D, SF12, Health Resource Use Questionnaires and HES (Hospital Episode Statistics) data

Overall study start date
01/01/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years
2. Able to provide written informed consent
3. FI for more than 6 months
4. Incontinent episodes of ≥ 2 per week
5. Suitable candidate for surgery, as judged by the operating surgeon (suitability assessment includes general fitness and conservative treatments for FI having proved ineffective.)
6. Suitable for either FENIX TM MSA or SNS
7. Anal sphincter defect < 180° as documented on endoanal ultrasound scan
8. Able and willing to comply with the terms of the protocol including Quality of Life (QoL) questionnaires

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350

Total final enrolment
99

Key exclusion criteria
1. Previous interventions for FI i.e. SNS, FENIX TM MSA or ABS
2. Chronic gastrointestinal motility disorders causing incontinence due to diarrhoea
3. Obstructed defaecation, as defined by an inability to satisfactorily evacuate the rectum (Obstructed Defecation score(OD-score) >8)
4. Anal sphincter defect ≥ 180°, as documented on endoanal ultrasound scan
5. An electric or metallic implant within 10cm of anal canal
6. Co-existent systemic disease (e.g. scleroderma, etc.) impacting on continence
7. Active anorectal sepsis
8. Diagnosis of colorectal or anal cancer within 2 years
9. External rectal prolapse
10. Significant scarring of the anorectum that, as judged by the treating surgeon, would prohibit FENIX TM MSA implantation or put the patient at high risk of implant erosion
11. Pregnancy (It is the local surgeons responsibility to ensure this is assessed in women of child-bearing potential according to local standard of care.)
12. Immunocompromise, including haematological abnormalities and treatment with steroids or other immunomodulatory medicines.
13. Congenital spinal abnormalities, preventing SNS implantation
14. Known requirement for future Magnetic Resonance Imaging (MRI) surveillance, which would be contraindicated in the presence of metallic implant
15. Suspected or known allergies to titanium

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
c/o Miss Julie Croft, Senior Trial Manager
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	HTA report	01/03/2021	24/03/2021	Yes	No
HRA research summary			28/06/2023	No	No