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Anal Sphinkeeper in patients with faecal incontinence: a multicentre prospective evaluation in the UK

Submission date 26/10/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/11/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/03/2024	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Sphinkeeper is a new artificial anal sphincter designed for the treatment of faecal incontinence. Faecal incontinence (inability to hold your stools) is a debilitating condition, which often occurs due to the sphincters in the bottom not working properly. Sphinkeeper surgery involves implanting specifically designed self-expandable implants into the bottom, essentially creating a doughnut which acts like a new strong, artificial bottom sphincter. Its use has been approved in the UK for patients with faecal incontinence and patients currently are already benefiting from its application. There is a need to collect long-term data on the faecal incontinence results as well as the surgery results and complications of the patients receiving Sphinkeeper treatment. The aim is to record the data of all patients receiving this treatment. This is because we need to know how effective this treatment is.

Who can participate?
All patients receiving Sphinkeeper surgery for faecal incontinence

What does the study involve?
Patients participating in this study will have their faecal incontinence assessed by filling in questionnaires before surgery and after surgery in three time periods:
1. The period immediately after surgery (1-30 days after surgery)
2. After 6 months
3. After 12 months

What are the possible benefits and risks of participating?
Participation in this study does not pose any benefits or risk to participants, as it only requires completion of questionnaires.

Where is the study run from?
Poole Hospital (lead centre) and 7 other hospitals in the UK

When is the study starting and how long is it expected to run for?
May 2018 to December 2025

Who is funding the study?
Self-funded

Who is the main contact?
Andrew Clarke
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
SK01

Study information

Scientific Title
Anal Sphinkeeper in patients with faecal incontinence: a multicentre prospective evaluation of surgical outcomes and faecal incontinence following Sphinkeeper application for patients with faecal incontinence

Study objectives
Anal Sphinkeeper is a safe and effective method of treating faecal incontinence

Ethics approval required
Old ethics approval format

Ethics approval(s)

None required. The use of Sphinkeeper for clinical use in the UK has already been approved. This study just aims to collect prospective data on the surgical outcomes and faecal incontinence of patients that receive this treatment.

Study design
Prospective observational case series

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Patients participating in this study will be seen in the outpatient department before to discuss Sphinkeeper surgery. During this visit patients will have a full faecal incontinence history, past obstetric history and past gynaecological history taken. Co-morbidities will also will be recorded, along with all previous treatments for faecal incontinence. This will be followed by a detailed baseline faecal incontinence assessment including a faecal incontinence severity score and faecal incontinence quality of life score. Finally, a physical examination will be performed relevant to pelvic floor anatomy and all pre-operative investigations will be recorded. Patients opting for treatment with Sphinkeeper will be consented for their surgery and all their data to be used for the purpose of research routinely either on the pre-operative outpatient clinic or on the day of surgery. Sphinkeeper is a new artificial anal sphincter designed for the minimally invasive treatment of faecal incontinence. It involves implanting specifically designed self-expandable prosthesis into the inter-sphincteric space. Ten prostheses are implanted between the internal and external sphincters essentially creating a shape memory doughnut which acts like a third artificial anal sphincter. Its use has been approved in the UK for patients with faecal incontinence and patients currently are already benefiting from its application. Surgery and peri-operative care will carry on as normal and as per institution protocol. No alterations on the surgical pathway will be made as a result of this study. Relevant intra-operative data will be recorded. Following surgery patients will be followed up routinely three times to have their post-operative function assessed. These will occur at the following time intervals:
1. Immediate post-operative period (1-30 days after surgery)
2. At 6 months
3. At 12 months after surgery
Each clinic appointment is estimated to take between 15-30 minutes. During this period data on faecal incontinence scores will be collected as well as on surgical outcomes and complications. A detailed study proforma with all the data collected can be provided on request. Patient participation will end after the third post-operative follow up appointment at 12 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SphinKeeper®

Primary outcome(s)
Faecal incontinence, assessed using the following at baseline and at 6- and 12-months post-operatively:
1. Vaizey/St Mark's score
2. Faecal incontinence quality of life score

Key secondary outcome(s))
1. Post-operative complications such as peri-prosthetic abscess or anal fistula measured in the immediate post-operative period (1-30 days post-operatively)
2. The correct distribution of the implants measured by endoanal ultrasonography intra-operatively, in the immediate post-operative period and at 6 and 12 months post-op
3. Anorectal physiology with rest and squeeze pressures recorded pre-operatively and at 6 and 12 months post-op

Completion date
23/12/2025

Eligibility

Key inclusion criteria
All patients receiving Sphinkeeper surgery for faecal incontinence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients unable to give consent

Date of first enrolment
01/11/2018

Date of final enrolment
01/11/2020

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Poole Hospital NHS trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
St Marks Hospital and Academic Institute
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Nottingham University Hospitals
Lister Road
Nottingham
United Kingdom
NG7 2FT

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Clatterbridge Road
Wirral
United Kingdom
CH63 4JY

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Marshalls Cross Road
St Helens
United Kingdom
WA9 3DA

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Barts Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1BB

Study participating centre
Neville Hall Hospital
Brecon Road
Abergavenny
United Kingdom
NP7 7EG

Sponsor information

Organisation
Poole Hospital

ROR
https://ror.org/00ph04139

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes