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Investigating a novel device as a treatment for fistula-in-ano

Submission date	Recruitment status	[_] Prospectively registered
24/02/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2024	Digestive System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Fistula in ano (FIA) is an abnormal tunnel between the inside of the lower bowel and the skin next to the anus. At least 12,000 people are newly diagnosed with the condition each year in the UK. The FIA condition often starts with an infected gland generating pus, which forms a tunnel to drain away. It is difficult to treat surgically without risking damage to sphincter muscles leading to incontinence. Currently, a plastic seton is used to keep the tunnel open, allowing the pus to drain and the tissue to recover from infection. Sometimes FIA tracts can heal after a period of recovery with a seton in place. Other times, the patient continues to develop abscesses and the seton cannot be easily removed and the FIA persists.

There are treatments available to attempt to get rid of the tract altogether, but these have a huge variation in success rate and a high risk of recurrence. This means that FIA can be difficult to manage and may require multiple operations.

We have developed a new device to tackle this condition. This is a small thin piece of material designed to be placed in the fistula tract. It works in much the same way as a conventional seton to drain the infectious material. What is unique about the new device is that it is made of a special scaffold material that encourages the body's cells to migrate and settle into the fistula tract, which is the first step in a process that eventually leads to complete healing. This scaffold material and the thin thread slowly dissolve away over several months, and any leftover material will simply fall off. This application relates to the first-in-man study of the new device, to assess its safety and patient acceptability.

Who can participate?
Adults over 18 years, requiring treatment for FIA.

What does the study involve?
This is a feasibility study looking at a new device designed for the treatment of FIA, which is a debilitating condition causing chronic inflammation and distress to millions of people around the world. Participants will have either conventional FIA treatment or will have the new device placed in the theatre under a general anaesthetic. All participants will undergo the same clinic appointments and number of operations. Participants will also be asked to complete quality-of-

life questionnaires periodically and a short interview at baseline and over a 3-month follow-up period.

What are the possible benefits and risks of participating?
The new device may be more effective and shorten the treatment pathway for patients with FIA.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust, Birmingham (UK)

When is the study starting and how long is it expected to run for?
March 2019 to June 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Professor Tom Pinkney, thomas.pinkney@uhb.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46237

Study information

Scientific Title
A clinical investigation of a novel Seton Device to treat fistula-in-ano

Study objectives
This novel device will provide a safe and potentially effective treatment option which is acceptable for both patients and clinicians.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2020, London - Stanmore REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; stanmore.rec@hra.nhs.uk), ref: 20/LO/0896

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Surgical procedure to treat fistula in ano (anal fistula)

Interventions
This prospective cohort study will run for a total of 1-year duration. We aim to recruit in 6 months, with a follow-up of each patient for 3 months and 3 months for buffer, analysis and write-up. The study is designed to assess the safety and comfort of the new device within the established treatment pathways for FIA disease. All recruited patients will have the same pre-operative and outpatient care, the only difference is that for the treatment group, patients will receive the new device in place of standard treatment. This way, we minimise the additional risks to patients who will have the device (as they will have the same scans, operations and general anaesthetics as patients who are on the standard pathway), and we also minimise other factors that may affect study observations or patients' qualitative interview results.

Patients we are aiming to recruit are:
- Patients newly diagnosed with FIA that require treatment (n=10)
- Patients with an existing draining seton that is at the stage of healing treatment (n=10)

- Control group: patients that have been newly diagnosed or are at the stage of healing treatment that will go onto have standard treatment (n=5)

Adult patients (>18 years old) with cryptoglandular (abscess/infected gland) fistula disease will be recruited. Patients who have s secondary cause for the fistula including inflammatory disease such as Crohn's, those with known allergies to device materials and those who cannot consent will be excluded.

Upon recruitment and completion of consent, patients will be asked to complete the EQ-5D-5L quality of life questionnaire at baseline. They will be placed onto a waiting list for an examination under anaesthesia for treatment of their FIA. Patients with a new FIA will receive the device as a primary treatment. Patients with an existing draining seton will receive the device as a change of seton and patients in the control group will undergo standard treatment as per standard practice of their consultant.

The new device is a long thin device that mimics the general shape of a standard seton and so can be inserted in the same way. The insertion of the new device will be as per the normal practice of the surgeon who is in the theatre performing the procedure - to adhere to a method that the surgeon is familiar with and practised in.

The patients will then be asked to keep a patient diary at weeks 1, 2, 3, 4, 6, 8, 10 and 12. This patient diary will explore the patient's quality of life through the EQ-5D-5L questionnaire and also assess their comfort and pain (Likert scale). The patients will be asked to note in their diary if or when their new device falls out and take a picture of their fallen-out device if possible. Patients will be given the option to complete the patient diary on the phone with a member of the research team.

At 12 weeks, the patients will be invited for a clinic assessment. At this appointment, a clinical assessment for FIA external opening site will be made and the patient will undergo a short semi-structured interview to qualitatively assess their impression of the device, FIA disease as a whole and their thoughts on what constitutes healing.

In summary, the only extra event/activity is the 12-week extra clinic appointment/qualitative interview.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Seton Device

Primary outcome measure
1. Safety –continuous monitoring of any adverse events and review compared to standard treatment at study end
2. Performance – clinical examination of fistula wound at 12 weeks

3. Usability – diary and pain and comfort questionnaire at weeks 1, 2, 3, 4, 6, 8, 12
4. Patient acceptability –diary and pain and comfort questionnaire at weeks 1, 2, 3, 4, 6, 8, 12
5. Clinician acceptability – questionnaire completed post-implant surgery

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2019

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Requires treatment for a fistula in ano
2. Patients over 18 years old
3. Patients with FIA resulting from cryptoglandular pathology

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 25; UK Sample Size: 25

Total final enrolment
20

Key exclusion criteria
1. Patients with proven inflammatory bowel disease
2. Patients who are unable to give consent
3. Patients with known allergies to PLLA or Polysorb sutures
4. Patients who are pregnant, attempting to conceive or breastfeeding

Date of first enrolment
20/03/2021

Date of final enrolment
20/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: II-LB-1116-20006

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.1	16/07/2020	06/04/2021	No	Yes
HRA research summary			28/06/2023	No	No