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The Fistula-In-Ano Trial comparing Surgisis® anal fistula plug versus surgeon's preference (advancement flap, fistulotomy, cutting seton) for transsphincteric fistula-in-ano

Submission date
28/07/2009

Recruitment status
No longer recruiting

Registration date
08/10/2009

Overall study status
Completed

Last Edited
11/03/2021

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An anal fistula is a small channel that develops between the end of the bowel and the skin near the anus. Common symptoms include skin irritation, pain, and a discharge of pus or blood when having a bowel movement. Anal fistulas are usually classed as either low or high depending on its position and how close it is to the sphincter muscles (the rings of muscles that open and close the anus). Most are low fistulae and are amenable to treatment, but high fistulae pose a difficult problem. Traditional surgical methods of cutting open the whole length of the fistula (fistulotomy) cut that portion of the sphincter involved in the fistula and put the patient at risk of permanent faecal incontinence. A variety of new procedures have been advocated to prevent this but none have achieved high healing rates combined with a low incidence of incontinence. The Surgisis® anal fistula plug has the advantages that it's simple to insert with minimal patient discomfort and the anal sphincter is preserved, with the potential for retaining full continence. However, the plug is relatively expensive and to justify its use we need to have more data regarding its effectiveness. This study will compare the continence and quality of life of patients treated with the Surgisis® anal fistula plug versus the standard treatment (surgery).

Who can participate?
Patients aged over 18 with high anal fistula (fistula tracts over 2 cm long, only one internal opening).

What does the study involve?
Most of the treatment patients receive is the same as they would receive if they were not in the study. There are no extra clinic visits, blood tests, or operations required beyond normal care. There is however some additional information that we would need to collect about the treatment and its effects. Patients are required to undergo an MRI scan and an examination under anaesthetic to assess the fistula; both of these are routine for patients with high anal fistula. If the fistula is suitable for treatment with a fistula plug, patients are asked to participate in the study. Participants are randomly allocated to be treated with either the standard

treatment (surgery) or insertion of a fistula plug. Participants allocated to standard surgical treatment decide with their doctor which of the four types of surgery is best for them. After treatment we collect information about any complications, whether the fistula has healed, any change in continence, and we ask participants to complete a short questionnaire on their quality of life. Most of this information is collected at routine out-patient appointments, although some information may be collected by means of questionnaires sent by post. All information collected is strictly confidential in the same way as other medical records. Participants also undergo a second MRI scan one year after treatment. This second MRI scan is not part of routine care and is performed to determine whether or not the fistula has healed. After that, the participants' progress is followed-up once a year.

What are the possible benefits and risks of participating?
There are no direct benefits from participating in the study. It is not clear whether fistula plugs are better or worse than conventional treatment; it is one of the aims of the study to find this out. A possible benefit of the fistula plug is that it will not affect continence. We cannot promise the study will help but participation in the study will provide valuable information on the treatment of anal fistula, and this will be used for the benefit of future patients.

Where is the study run from?
The study is run within 47 hospitals within the UK. The lead site is St James's University Hospital, Leeds. The study is coordinated through the Birmingham Clinical Trials Unit, University of Birmingham.

When is the study starting and how long is it expected to run for?
November 2010 to May 2017.

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

Who is the main contact?
Prof. David Jayne
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Study website
http://www.bctu.bham.ac.uk/fistula/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/89/01; 3.1 (Dated 07/04/2014)

Study information

Scientific Title
Surgisis® anal fistula plug versus surgeon's preference (advancement flap, fistulotomy, cutting seton) for transsphincteric fistula-in-ano: a multicentre phase III randomised controlled trial

Acronym
FIAT

Study objectives
The FIAT trial is a pragmatic, multi-centre, randomised controlled trial designed to provide reliable evidence on the value of the Surgisis® anal fistula plug in the treatment of high fistula-in-ano.

The study will evaluate the clinical and cost-effectiveness of the Surgisis® anal fistula plug against the standard surgical techniques routinely used to treat cryptogenic transsphincteric anal fistulae. The standard surgical techniques have been grouped as a single comparator and termed "Surgeon's Preference", and include the use of advancement flap, fistulotomy, or a cutting seton. Efficacy will be measured in terms of preservation of symptom-specific quality of life (QoL), fistula healing rates, faecal incontinence scores, complication and re-intervention rates, and heath economics and cost-effectiveness.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/078901
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/51939/PRO-07-89-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 07/06/2010, ref: 10/H0405/29

Study design
Multicentre phase III 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

Health condition(s) or problem(s) studied
High transsphincteric fistula-in-ano

Interventions
Fistula plug versus surgeon's preference which can be either:
1. Advancement flap
2. Fistulotomy
3. Cutting seton
4. LIFT Procedure (added 06/01/2016)

Total duration of treatment: The patient will be randomised and then have surgery within that week. They will then be followed up at 6 weeks, 6 months and 12 months.

Total duration of follow-up: Currently funded to follow all patients up to 12 months but this will be extended for annual follow-up until at least 3 years.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Symptom-specific quality of life as assessed by the validated Faecal Incontinence Quality of Life Scale and supplemented with collection of generic EQ-5D data and visual analogue scores. Assessments will be at baseline, 6 weeks, 6 and 12 months.

Secondary outcome measures
1. Fistula healing rate at 12 months
2. Faecal incontinence at baseline, 6 and 12 months
3. Complication rates
4. Re-intervention rates
5. Health resource utilisation
6. Cost-effectiveness

Overall study start date
05/01/2010

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Clinical diagnosis of high transsphincteric cryptoglandular fistula-in-ano. A high transsphincteric fistula is defined as a fistula involving greater than or equal to 1/3 of the external anal sphincter muscle as assessed by clinical examination or radiological imaging.
2. Patients must have undergone a prior examination under anaesthesia (EUA) to characterise the nature of the fistula
3. The fistula tract should be greater than 2 cm in length
4. Patients must have been treated with a draining seton for a minimum period of 6 weeks prior to randomisation
5. Patients must be 18 years or older, either sex, and able to provide informed consent
6. Fistulae must be cryptoglandular aetiology

Added 06/01/2016:
7. Only a single internal fistula opening should be present at EUA, such that the fistula is suitable for treatment by insertion of a single fistula plug

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
306

Total final enrolment
304

Key exclusion criteria
1. Unable/unwilling to provide informed consent
2. Contraindication to general anaesthesia
3. Low transsphincteric fistulae involving less than 1/3 of the external anal sphincter
4. Non-cryptoglandular fistulae, e.g. Crohns, obstetric, irradiation, malignant, etc.
5. Other perineal fistulae, e.g. rectovaginal fistulae, pouch-vaginal fistulae, etc.
6. Evidence of active perianal sepsis
7. Cultural or religious objection to the use of pig tissue

Added 06/01/2016:
8. Complex disease in which more than one internal fistula opening is present and requiring concurrent insertion of more than one fistula plug
9. Absolute contraindication to MRI scan e.g. cardiac pacemaker
10. Patients with recurrent anal fistulae previously treated with a fistula plug

Date of first enrolment
01/05/2011

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Surgical Unit
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
-
Leeds
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United Kingdom
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

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
To be confirmed at a later date

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan

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	results	01/05/2019	23/05/2019	Yes	No
Results article	results	01/03/2021	11/03/2021	Yes	No