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Fistula-In-Ano trial (FIAT)

Welcome to the FIAT Trial website.

The FIAT Trial is currently open to recruitment!

The FIAT Trial will compare the Biodesign® Surgisis® anal fistula plug with the surgeon's preference; advancement flap, fistulotomy, cutting seton or the LIFT procedure, for the treatment of transsphincteric fistula-in-ano.

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The Rational for a Trial

Currently the Biodesign® Surgisis® anal fistula plug is being used on an ad hoc basis to treat a variety of fistulae based on limited scientific evidence for its efficacy. It costs more then standard treatments and there are legitimate concerns regarding reported healing and recurrence.

Recently NICE has reviewed the evidence for the fistula plug and concluded:

"Current evidence suggests that there are no major safety concerns associated with the closure of anal fistula using a suturable bioprosthetic plug. However, evidence on the efficacy and cost effectiveness of the procedure is not adequate for it to be used without special arrangements for consent and audit or research."

There is therefore an urgent need for a randomised controlled trial to evaluate the role of the anal fistula plug in the treatment of these high anal fistulae and to determine whether its higher initial cost as compared to other current techniques is justified in terms of better patient outcomes.

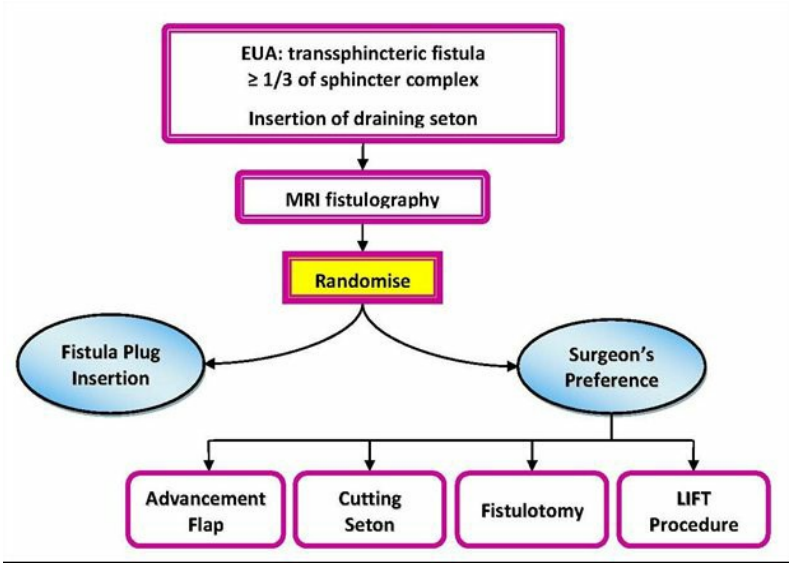
The Fistula-In-Ano Trial (FIAT) aims to address this knowledge gap by evaluating whether the fistula plug can produce relief of symptoms whilst maintaining anal sphincter function and preserving symptom-specific (incontinence) quality of life.

The information obtained by randomising 500 patients into FIAT will help guide the treatment of many thousands of future patients.

Trial Design

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

Patients with a confirmed high transsphincteric fistula at risk of incontinence with fistulotomy (involving approximately 1/3 or more of the external sphincter complex), will be randomised between insertion of the Biodesign® Surgisis® anal fistula plug and the surgeon's preference of advancement flap, cutting seton, fistulotomy and the LIFT procedure.



Objectives

FIAT is a pragmatic, Phase III multi-centre randomised controlled trial with the following objectives:

Primary objective:

To compare the Biodesign® Surgisis® anal fistula plug with standard treatments for high transsphincteric anal fistulae in terms of:

- symptom-specific quality of life

Secondary objectives:

To compare the Biodesign® Surgisis® anal fistula plug with standard treatments for high transsphincteric anal fistulae in terms of:

- fistula healing rates
- complication and re-intervention rates
- faecal incontinence rates
- cost-effectiveness
- health economic benefits

Outcome Measures

Primary outcome measures:

The primary outcome measures relate to quality of life and are assessed at baseline, 6 weeks, 6 and 12 months:

1. The Faecal Incontinence Quality of Life scale
2. EQ-5D (EuroQoL)

Symptom-specific quality of life has been chosen rather then fistula healing rates as it reflects the primary aim of fistula surgery: to produce symptom relief whilst maintaining anal sphincter function and preserving symptom specific QoL.

Secondary outcome measures:

The secondly outcome measures are:

1. Fistula healing rate at 12 months
2. Faecal incontinence rates (St Marks Incontinence Score) at baseline, 6 months and 12 months
3. Complication rates at 6 weeks, 6 months and 12 months
4. Rates of re-intervention at 6 weeks, 6 months and 12 months
5. Generic quality of life assessed using EuroQoL EQ-5D and visual analogue scale scores at baseline, 6 weeks, 6 months and 12 months.

Surgeon and Radiology Workshops

We have now held all of our planned Surgeon and Radiology workshops

If you would like to participate in the FIAT Trial, but were unable to attend the workshops, please contact the **FIAT Trial office (mailto:fiat@contacts.bham.ac.uk)** .

Email: **FIAT@contacts.bham.ac.uk (mailto:fiat@contacts.bham.ac.uk)**

Tel: 0121 415 9104

Fax: 0121 415 8871

How to get involved

If your site would like to participate in the FIAT Trial, then please download and complete the **FIAT Site Registration Form (/Documents/college-mds/trials/bctu/fiat/FIATGeneralDocuments/FIAT-SiteRegistrationForm.pdf)** and send it to the FIAT Trial office

Alternatively for further information please contact the **FIAT Trial Office (mailto:fiat@contacts.bham.ac.uk)**

Email: **FIAT@contacts.bham.ac.uk (mailto:FIAT@contacts.bham.ac.uk)**

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