FIAT

Synopsis of the FIAT Trial – The Fistula–In–Ano Trial

FIAT Trial

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

The Rationale for a Trial

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 for audit or research".

There is thus an urgent need to formally evaluate the role of the fistula plug in the treatment of 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.

Trial Design

FIAT is a multi-centre randomised controlled trial randomising between surgeon's preference and the anal fistula plug. FIAT aims to recruit 500 patients over 3 years; a total of 400 patients will need to be recruited in a 1:1 ratio to allow detection of a small to moderate treatment effect. To allow for a 20% non-compliance rate, it is aimed to recruit a total of 500 patients.

Trial Objectives

The primary objective of the trial is to assess if, in the treatment of fistula-in-ano, the anal fistula plug:

- Improves symptom-specific quality of life

The secondary objectives are:

- To assess if use of the plug improves fistula healing rates
- To assess if there is an improvement in faecal continence
- To assess if there is a reduction in re-intervention rates
- To assess the nature and frequency of complications
- To assess the cost-effectiveness of the plug

Eligibility Criteria

Inclusion criteria

- Clinical diagnosis of high transsphincteric cryptoglandular fistula-in-ano.
- Prior examination under anaesthesia (EUA) to characterise the nature of the fistula.
- Fistula tract ≥ 2cm in length.
- Single internal fistula present at EUA treatable by insertion of a single fistula plug.
- Patients must have been treated with a draining seton for a minimum period of 6 weeks prior to randomisation.
- Aged 18 years or older and able to provide informed consent.
- Fistulae must be cryptoglandular aetiology.

Exclusion criteria

- Low transsphincteric fistulae involving < 1/3 of the external anal sphincter.
- Non-cryptoglandular fistulae e.g Crohns, obstetric, irradiation, malignant etc.
- Other perineal fistulae e.g rectovaginal fistulae, pouch-vaginal fistulae etc.
- Complex disease in which more than one internal fistula opening is present.
- Evidence of active perianal sepsis
- Contraindication to general anaesthesia.
- Cultural or religious objection to the use of pig tissue.
- Absolute contraindication to MRI scans.
- Recurrent anal fistulae previously treated with a fistula plug.
- Unable or unwilling to provide informed consent.

Primary Outcome Measures

1. Symptom-specific Quality of life (QoL): Symptom-specific QoL will be 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 undertaken at baseline, 6 weeks, 6 and 12 months. The 6 week assessment will also include questions relating to health at discharge.

Secondary Outcome Measures

1. Fistula healing rate at 12 months: Assessed at 12 months in all patients and radiologically using MRI. A fistula will be deemed to be healed clinically if the patient is symptom-free, there is no evidence of on-going perianal sepsis, and no evidence of a residual internal or external fistulous opening. MRI evidence of fistula healing will include the absence of active inflammation or sepsis.
2. Faecal incontinence: Assessed using the St Marks Incontinence Score at baseline, 6 & 12 mnths
3. Complication rates: all procedure-related and -unrelated complications will be reported.
4. Re-intervention rates: to include re-operations for complications or further fistula treatment
5. Health resource utilisation: to also include non-trial expenditures relating to symptoms.
6. Cost-effectiveness.

How to get involved

Contact the Trial Manager, Dr Laura Magill at the FIAT Trial Office by e-mail e.l.magill@bham.ac.uk or by telephone: 0121 415 9105.