

Randomised controlled trial of fissurectomy and botulinum toxin injection versus island flap in the management of chronic anal fissure

Submission date 29/09/2006	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 06/10/2011	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0213168035

Study information

Scientific Title

Study objectives

To determine whether fissurectomy and botox injection or island advancement flap is superior in the surgical management of chronic anal fissure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Fissurectomy

Interventions

Anal fissure is a painful type of ulcer around the anal canal. It often does not respond to topical therapy and surgery has to be considered. Current treatment has a risk of incontinence after surgery. We wish to look at two different kinds of surgery which do not have any risk of disturbing continence, and decide which is superior in managing anal fissure. The first is surgical removal of the fissure together with an injection of botox. The second is surgical removal of the fissure with a flap of skin to cover the wound. Both techniques avoid cutting of the 'sphincter' and so do not disturb continence.

Added 28 August 2008: trial stopped due to poor recruitment.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Healing rates of anal fissure at 4, 12 and 24 weeks post surgery.

Key secondary outcome(s)

1. Pain on defecation as assessed by Visual analogue score for 10 days post surgery
2. Patient's general health as assessed by SF-12 questionnaire at 24 weeks
3. Continence at 4, 12 and 24 weeks post surgery as assessed by the Cleveland incontinence score

Completion date

06/04/2007

Reason abandoned (if study stopped)

Poor recruitment

Eligibility

Key inclusion criteria

1. Chronic anal fissure resistant to 6 weeks GTN therapy
2. Features of fissure chronicity (skin tag, induration)
3. Suitable for day case surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Concurrent peri-anal disease
2. Previous fissure surgery

Date of first enrolment

01/08/2005

Date of final enrolment

06/04/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal West Sussex NHS Trust

Chichester

United Kingdom

PO19 6SE

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Royal West Sussex NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration