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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

Study design
Randomised controlled trial

Primary study design
Interventional

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