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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Stopped	
Last Edited 06/10/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/08/2005

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
35 patients in each arm.

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration