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A prospective randomised study comparing lateral internal sphincterotomy with anal dilatation in the treatment of anal fissures.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/11/2013	**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
N0084144571

Study information

Scientific Title

Study objectives
Are Lateral Internal Sphincterotomy (LIS) and Anal Dilatation for the treatment of anal fissures both acceptable procedures giving equal results?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Prospective randomised study

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Surgery: Anal fissure

Interventions
Patients diagnosed as having anal fissure who have been advised to have surgery for the same, and who have agreed to such advice and fulfil the inclusion criteria will be invited to take part in the study until sample size is achieved.

Lateral internal sphincterotomy vs anal dilatation

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
1. The patient will be required to record all intake of Tramadol on the data collection sheet. The usage of as required medication would be used to calculate the difference in analgesic requirement between the two groups.
2. Anal incontinence will be assessed by the New St. Marks Score, extent of healing will be scored on a scale from 1 to 3, 1=no healing, 3=complete healing.
3. Pain scores on a numerical rating scale 0-10 will be collected from the patient as notes on day 1, day 5 and day 10.

Key secondary outcome(s)
Not provided at time of registration

Completion date
30/06/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
02/06/2003

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern Lincolnshire & Goole Hospitals NHS Trust
Scunthorpe
United Kingdom
DN15 7BH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Northern Lincolnshire and Goole Hospitals 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