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

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>25/11/2013 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Study design
Prospective randomised study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Not Specified

### Participant information sheet

### 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 measure

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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
02/06/2003

### Completion date
30/06/2004

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
The aim of this study is to recruit 30 patients in each group to allow for patients lost to follow up and for patients who withdraw from the trial.

### 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
England

United Kingdom

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

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
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**Sponsor type**
Government

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

# Funder(s)

**Funder type**
Government

**Funder Name**
Northern Lincolnshire and Goole Hospitals 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