

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

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| <b>Submission date</b><br>30/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>30/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>25/11/2013       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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

**Study design**

Prospective randomised study

**Primary study design**

Interventional

**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