# A prospective randomised study comparing 'standard open' haemorrhoidectomy with the 'completely closed and sutured' technique.

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
11/04/2014	Surgery	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Mr Muzaffar Ahmad

#### Contact details

Northern Lincolnshire & Goole Hospitals NHS Trust Scunthorpe General Hospital Cliff Gardens Scunthorpe United Kingdom DN15 7BH

# Additional identifiers

Protocol serial number N0084144553

# Study information

Scientific Title

## Study objectives

Does the completely closed and sutured technique of haemorrhoidectomy reduce discomfort and enhances healing in comparison to the standard open method?

## 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: Haemorrhoidectomy

#### **Interventions**

All patients diagnosed as having grade 3 or 4 haemorrhoids and require corrective surgery who fulfil the inclusion criteria seen in the general surgical outpatient department of Scunthorpe And Goole hospitals will be invited to take part in the study until the sample size has been achieved. After patients have agreed to participate, they will be randomised into one or other of the treatment arms: 'standard open' haemorrhoidectomy vs 'completely closed and sutured' technique.

## **Intervention Type**

Procedure/Surgery

#### Phase

Not Specified

# Primary outcome(s)

- 1. A routine follow up clinical appointment will be sent to the patient at 4 weeks after surgery. Extent of healing will be scored on a scale from 1-4. (1:<25%; 2:25-50%; 3:50-75%; 4:complete healing).
- 2. Post operative SF 36 questionnaire at 4 weeks after surgery
- 3. Duration in days taken to return to normal daily activities
- 4. Percent satisfaction after the procedure
- 5. Consent to undergo the procedure again if required

# Key secondary outcome(s))

Not provided at time of registration

# Completion date

02/01/2004

# **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

02/01/2002

## Date of final enrolment

02/01/2004

# **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