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	[] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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: 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 measure

- 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

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/01/2002

Completion date

02/01/2004

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

With reference to previously published studies, comparing open versus stapled techniques a similar sample size n=20 in each arm was arrived at.

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

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 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

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 summaryNot provided at time of registration