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

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 11/04/2014	**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

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
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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SW1A 2NL
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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