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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

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