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A randomised trial of open vs closed haemorrhoidectomy on the same patient

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 12/04/2011	**Condition category** Surgery	

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
N0515150705

Study information

Scientific Title

Study objectives
Which of the two most popular surgical techniques for removing haemorrhoids causes least pain, and fastest healing?

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
Patients will be fully informed about the project and written consent will be obtained prior to their enrollment in the study. Operations will be carried out under general anaesthetic, either as a day case procedure, or as an inpatient as appropriate. At the time of operation the haemorrhoids will be assessed, and each haemorrhoid swelling randomised to either the 'open' or 'closed' procedure by the toss of a coin. The haemorrhoid will be removed according to the technique randomly chosen. The haemorrhoid on the opposite side of the anus will have the other procedure performed. Any further haemorrhoids will be randomised in the same way. The operative techniques for the two procedures will be standardised so all surgeons operating in the study perform them in the same way.
An established protocol will be used for the preoperative and postoperative management of the patients. This will include 3 days of lactulose (a stool softener) prior to the operation, and a discharge pack of lactulose, metronidazole (an antibiotic which has been found to help with pain relief after such operations), diltiazem cream (which relaxes the sphincter, relieving post operative pain) and diclofenac (a painkiller). This is the standard regime for all patients having

haemorrhoid surgery. After the operation, patients will be given a diagram of the positions of the removed haemorrhoids. They will be asked to rank the wounds in order of painfulness at the end of each day. They will also be asked to complete daily pain scores on a 10cm visual analogue scale, recording both experienced and expected pain. The day of the first post operative bowel action will also be recorded, as well as pain scores for this and subsequent bowel actions. Patients will be asked to keep diary cards for the two weeks following their operation. Patients will be assessed in the Outpatient clinic at 2 weeks, 6 weeks and 6 months following the operation. At these appointments any complications will be noted, and the wounds inspected. At the two week appointment a digital photo will be taken of the healing wounds. These will be assessed by a blinded observer and marked on a scale of 1 to 10 (with 1 being complete healing, and 10 being very poor wound healing.) The time taken to return to normal activities and work will also be recorded.

Added July 2008: the trial was stopped due to lack of participants.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Results of the haemorrhoidectomy technique used in terms of post operative pain scores and healing rates.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
01/03/2006

Reason abandoned (if study stopped)
Lack of participants

Eligibility

Key inclusion criteria
Patients undergoing haemorrhoidectomy for symptomatic Grade III and Grade IV haemorrhoids. The Chief Investigator will approach the patients in clinic or on the ward and explain the study with both verbal and written information. Those patients willing to participate in the study will be recruited following a full explanation of what is involved and written consent.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2004

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West London Hospitals NHS Trust
Harrow
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
North West London Hospitals NHS Trust (UK)

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