

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

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 12/04/2011	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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

North West London Hospitals NHS Trust

Harrow

United Kingdom

HA1 3UJ

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Government

Funder Name

North West London Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration