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The eTHoS study (haemorrhoids treatment): either Traditional Haemorrhoidectomy or Stapled Haemorrhoidopexy for haemorrhoidal disease

Submission date
25/02/2010

Recruitment status
No longer recruiting

Registration date
08/03/2010

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Haemorrhoids (also called piles) are swellings around the back passage that can cause bleeding, pain and itching and can protrude. When they become enlarged, surgery is often advised as it is an effective way to control the symptoms. There are two major surgical treatments for haemorrhoids: traditional surgery and a surgical treatment in which the haemorrhoids are stapled. The current (traditional) surgical treatment for haemorrhoids involves removal of the swellings in order to improve symptoms. This traditional approach is effective but it is often associated with pain immediately after surgery.
Newer surgical techniques include the stapled treatment. The surgery involves cutting away a ring or donut of tissue above the swellings and special staples are used to join the tissue again. The advantages of the stapled treatment include a possible reduction of pain immediately after surgery, shorter operating time and hospital stay and a quicker return to work. However, over the longer term, patients who have this type of surgery may be more likely to experience haemorrhoids again and need further surgery. Both surgical treatments are commonly performed as a hospital day-case or inpatient admission by colorectal surgeons and, in general, both are successful in improving patients symptoms. At present there is no evidence that tells us which of these types of surgery is best for patients who have haemorrhoids that require surgery. This study will investigate which of the two surgeries is the best surgical treatment for different kinds of patients.

Who can participate?
Patients who have haemorrhoids and have been told that surgical treatment is required to improve symptoms can take part, if the hospital where they will be treated is taking part in the study. We hope that about 800 patients will take part and complete this study in the UK.

What does the study involve?
Patients will be divided into two treatment groups. Patients in group 1 will receive traditional surgery and patients in group 2 will receive stapled surgery. The researchers will then compare

the general health and quality of life of the people in these two treatment groups over the same amount of time. The treatment group that participants are put in will be decided at random by a computer programme. This means that neither the participant nor the doctors will be able to decide which surgical treatment participants will receive. This method is used to make sure that the groups of participants who receive the two types of treatment are very similar. Because we do not know which treatment is best, everyone has an equal chance of receiving the treatment that is shown to be most effective once the study is completed. To take part in this study participants must be happy to be in either of the treatment groups. After the surgery, the study will collect information from all the patients who take part in the study for five years after surgery. In research this is called follow-up. Everyone in the study will be followed-up in exactly the same way. Patients who take part in the study will return to the clinic at the hospital about 6 weeks after their operation. They will also be sent questionnaires from the central co-ordinating office in Aberdeen at around 1, 3 and 6 weeks and 12, 24 and 60 months after their operation. Patients will be sent reply-paid envelopes to return their questionnaires.

What are the possible benefits and risks of participating?
There may be no direct benefit to patients who take part but they will be helping doctors to assess which treatment is best. In the stapled surgical treatment group, the chance of having haemorrhoids again in the future may be higher than with traditional surgery. In the traditional surgical treatment group, potential risks may include more pain immediately after surgery, but this can usually be resolved with pain-reducing drugs. At present surgeons do not know if the risk of having a complication after surgery, such as bleeding, requirement of blood transfusion, anal stenosis or fissure, urinary retention, incontinence, wound or pelvic infection, is higher with one of these two procedures.

Where is the study run from?
The study is run by The Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen. Participants will be recruited at different hospitals throughout the UK.

When is the study starting and how long is it expected to run for?
The study started in November 2010 and recruitment of patients will end in July 2014. Participants will be followed-up for 5 years, so the follow-up of all participants will end in middle of 2019. The findings will be published in a report in Autumn 2019.

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
eTHoS Study Office
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Contact information

Type(s)
Scientific

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Protocol serial number
HTA 08/24/02

Study information

Scientific Title
A pragmatic multicentre randomised controlled trial comparing stapled haemorrhoidopexy to traditional excisional surgery for haemorrhoidal disease

Acronym
eTHoS

Study objectives
The study is investigating whether stapled haemorrhoidopexy (surgical) treatment improves clinical effectiveness and cost-effectiveness compared with traditional excisional haemorrhoidectomy.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/082402
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/52878/PRO-08-24-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, 17/06/2010

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Haemorrhoidal disease

Interventions

Participants will be randomised to either stapled haemorrhoidopexy (SH) or traditional haemorrhoidectomy (TH). The SH procedure involves excising a ring or "donut" of tissue above the haemorrhoidal cushions with immediate re-anastomosis of the mucosa using staples. TH involves excision of the haemorrhoidal cushions.

Patients will be followed-up in clinic approximately six weeks after their surgery. Postal questionnaires will be completed by participants at 1, 3 and 6 weeks after surgery and 1 and 2 years after randomisation. It is also the intention to follow-up participants in the longer-term through a 5-year postal questionnaire.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The trial has both a patient-centred and an economic primary outcome:
1. Patient-centred: quality of life profile (area under the curve derived from EQ-5D measurements at baseline, 1 week, 3 weeks, 6 weeks, 12 months and 24 months)
2. Economic: incremental cost per quality adjusted life year (QALY) gained with QALYs based on the responses to the EQ-5D at 24 months

Key secondary outcome(s))
Secondary outcomes include patient-reported, clinical and economic measures:

Patient-reported (collected at 1, 3, 6 weeks, 1 year, 2 years and 5 years):
1. Generic health profile measured by 36-item short form health survey (SF-36) and EQ-5D
2. Visual analogue scale (VAS) pain score
3. Cleveland incontinence score
4. Haemorrhoid symptom score
5. Post-operative analgesia consumption
6. Recurrence of haemorrhoids

Clinical (collected at the time of surgery and at 6-week clinical follow-up):
7. Peri- and post-operative complications including:
7.1. Haemorrhages
7.2. Requirement for blood transfusion
7.3. Anal stenosis, anal fissure
7.4. Urinary retention
7.5. Residual anal skin tags
7.6. Difficult defecation
7.7. Wound discharge
7.8. Pelvic sepsis
7.9. Pruritis

Economic:
Costs will be based on resource use data.
8. Costs to the NHS and patients at two years:
8.1. Time to recovery
8.2. Length of hospital stay
8.3. Use of health services for haemorrhoids related events or treatments
8.4. Patient costs (treatments], travel to health services, sick leave)
8.5. Need for alternative management for haemorrhoids (e.g., surgery, drugs)

8.6. Other use of health services:
8.6.1. Visits to GP
8.6.2. Visits to practice nurse
8.6.3. Visits to colorectal surgeon
9. Estimated lifetime cost to NHS and patient
10. QALYS estimated from the EQ-5D at 24 months
11. QALYS estimated over the patient's lifetime
12. Cost-effectiveness analysis (incremental cost per case of stapled haemorrhoidopexy and traditional haemorrhoidectomy excision avoided)

Completion date
30/09/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/01/2011:
1. Patient with circumferential haemorrhoids grade II, III and IV
2. Patients aged 18 years or older
3. Written informed consent obtained

Previous inclusion criteria:
1. Patients with haemorrhoids grade II who have failed traditional therapy (rubber band ligation [RBL]), haemorrhoids grade III and IV
2. Patients aged 18 years or older, either sex
3. Written informed consent obtained

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 01/02/2011:
1. Previous surgery for haemorrhoids (traditional or stapled) (except rubber band ligation (RBL) or Haemorrhoidal Artery Ligation Operation (HALO))
2. Pre-existing sphincter injury
3. Peri-anal sepsis
4. Inflammatory bowel disease
5. Malignant colorectal disease

6. Medically unfit for surgery or completion of the trial
7. Pregnant women

Previous exclusion criteria:
1. Previous surgery for haemorrhoids (except RBL for grade II)

Date of first enrolment
01/10/2010

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Raigmore Hospital
Inverness
United Kingdom
IV2 3UJ

Sponsor information

Organisation
Co-sponsored by University of Aberdeen (UK) and NHS Highland

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2016		Yes	No
Results article	results	01/11/2017		Yes	No
Protocol article	protocol	11/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes