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The HubBLe Trial: Haemorrhoidal Artery Ligation (HAL) versus Rubber Band Ligation (RBL) for haemorrhoids

Submission date 09/05/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/05/2012	**Overall study status** Completed	
Last Edited 06/11/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Haemorrhoids (piles) are common, with up to 1 in 3 people in the UK affected by them. Sometimes haemorrhoids can be controlled through diet but worse symptoms may need other treatments, such as rubber band ligation or surgery. This study aims to test two different treatments: Rubber Band Ligation (RBL) and Haemorrhoidal Artery Ligation (HAL), to see which should be used for treatment of grade II and III haemorrhoids in the future.

Who can participate?
Patients aged 18 years and over that have grade II or III haemorrhoids can be recruited to this research; patients must be presenting with haemorrhoids for the first time, or after failure of rubber band ligation treatment. They will be identified either by the general practitioner (GP) referral letter or by colorectal surgeons at the first clinic appointment and followed-up by the research nurse.

What does the study involve?
Patients will be randomised to one of the two treatments; half of the patients will have the RBL procedure and half will have the HAL operation. Both of the treatments being compared are already used in the NHS for treatment of haemorrhoids, and at the moment surgeons do not know which treatment is best in the long run for the treatment of grade II and III haemorrhoids. The study will look at the cost effectiveness of the two treatments including further treatment required for their symptoms, the patient's quality of life and some other measures relating to haemorrhoidal symptoms such as pain and continence. Patients will be required to complete a questionnaire 1 day, 7 days, 21 days, 6 weeks and 12 months following the trial procedure. The main outcome will be whether the patient has cured or improved symptoms or unchanged or worse symptoms 12 months after the trial procedure.

What are the possible benefits and risks of participating?
Patients taking part in this study will contribute to evidence that will help surgeons know which treatment to choose in the future. RBL is a commonly performed procedure in surgical outpatients; it does not require an anaesthetic and patients can go home the same day. This

procedure has a risk of complications, usually pain, and the likelihood of getting haemorrhoids again can be quite high.
HAL is a minor surgical procedure and although anaesthetic is required, recovery can be quick and the risk of complications seems to be low; it also appears that the likelihood of getting haemorrhoids again may be lower than for RBL. Both treatments can have side effects related to loss of blood, further symptoms related to haemorrhoids and pain. In very rare cases patients could get pelvic sepsis, or abscesses (collection of pus). There are also side effects related to the anaesthetic used for the HAL operation.

Where is the study run from?
The aim is to recruit 350 patients to the trial from up to 14 NHS trusts in England and Scotland. The lead centre will be the Sheffield Teaching Hospitals NHS Foundation Trust, who is the Sponsor for the research and also where the Chief Investigator is based. The research is being managed by the Clinical Trials Research Unit in the University of Sheffield.

When is the study starting and how long is it expected to run for?
Recruitment is planned to start at eight centres in October 2012, with the other centres starting recruitment by February 2013. The recruitment period will be one year, ending in September 2013. After the recruitment year, there will be another year for follow-up, and this will be completed in September 2014.

Who is funding the study?
NIHR - Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
HTA 10/57/46; Version 1.1, 12/06/2012

Study information

Scientific Title
A multi-centre randomised controlled trial comparing rubber band ligation with haemorrhoidal artery ligation in the management of symptomatic second and third degree haemorrhoids

Acronym
HubBLe

Study objectives
Haemorrhoidal artery ligation has a lower recurrence rate than rubber band ligation when used to treat second and third degree haemorrhoids.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/105746
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/81681/PRO-10-57-46.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Yorkshire REC, 13/06/2012, ref: 12/YH/0236

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Second and third degree haemorrhoids

Interventions
The intervention is either Rubber Band Ligation (RBL) or Haemorrhoidal Artery Ligation (HAL). Both interventions are established and well documented procedures.

Conventional RBL uses a simple suction device that is applied to each haemorrhoid via a disposable proctoscope. A rubber band is then fired onto the base of the haemorrhoid which constricts the blood supply causing it to become ischaemic before being sloughed approximately 1-2 weeks later. The resultant fibrosis reduces any element of haemorrhoidal prolapse that may have been present.

HAL uses a proctoscope modified to incorporate a Doppler transducer. This enables accurate detection of the haemorrhoidal arteries feeding the haemorrhoidal cushions. Accurate ligation of the vessels with a suture reduces haemorrhoidal engorgement. When combined with a 'pexy' suture, both bleeding and haemorrhoidal prolapse is addressed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Recurrence, defined as the proportion of patients with recurrent haemorrhoids at 12 months, as derived from a telephone assessment in combination with GP and hospital records. Patients who have undergone further treatment during the follow up period will be considered to have recurrent haemorrhoids.
Question to be asked:
'At the moment, do you feel your symptoms from your haemorrhoids are:
1. Cured or improved compared with before starting treatment; or,
2. Unchanged or worse compared with before starting treatment?'

Any patient who answers '1' but has required further treatment since the initial procedure will be reclassified as '2', identified via hospital records, their consultant, their GP and patient questioning.

Key secondary outcome(s))
1. Symptom score (before randomisation, 6 weeks, 1 year)
2. Quality of Life, EQ-5D (before randomisation, 1, 7, 21 days, 6 weeks, 1 year)
3. Continence questionnaire (before randomisation, 6 weeks, 1 year)
4. Pain score [Visual Analogue Scale (VAS)], before randomisation, 1, 7, 21 days, 6 weeks)
5. Health and social care resource use questionnaire (6 weeks, 1 year)
6. Complications review (6 weeks, 1 year)
7. Need for further treatment including details (6 weeks, 1 year)
8. Clinical examination findings if recurrence (6 weeks)

Completion date
30/09/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/04/2013:
1. Adults aged 18 years or over with symptomatic second or third degree haemorrhoids.

Previous inclusion criteria until 30/04/2013:
1. Adults aged 18 years or over with symptomatic second or third degree haemorrhoids
2. Either presenting for the first time or after failure of RBL

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 30/04/2013:
1. Patients that have had previous surgery for haemorrhoids (at any time)
2. Patients that have had more than one injection treatment for haemorrhoids in the past 3 years
3. Patients that have had more than one RBL procedure in the past 3 years
4. Patients with known perianal sepsis, inflammatory bowel disease, colorectal malignancy, pre-existing sphincter injury
5. Patients with an immunodeficiency
6. Patients that are unable to have general or spinal anaesthetic
7. Patients currently taking Warfarin Clopidogrel or have any other hypocoagulability condition
8. Patients currently taking Nicorandil
9. Pregnant women
10. Patients that are unable to give full informed consent (this may be due to mental capacity or language barriers)
11. Patients previously randomised to this trial

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Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern General Hospital
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/018hjpz25

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	23/07/2016		Yes	No
Results article	results	01/11/2016		Yes	No
Protocol article	protocol	25/10/2012		Yes	No

Other publications	lessons learnt	01/11/2019	06/11/2019	Yes	No