

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

<b>Submission date</b> 09/05/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/11/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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?

Katie Biggs

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## Contact information

### Type(s)

Scientific

### Contact name

Mr Steven Brown

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

HubBL

## 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](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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## 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 measure**

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.

## **Secondary outcome measures**

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)

## **Overall study start date**

01/10/2012

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

350

**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

Previous exclusion criteria until 30/04/2013:

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6. Pregnant women
7. Patients that are unable to give full informed consent (this may be due to mental capacity or language barriers)
8. Patients previously randomised to this trial

**Date of first enrolment**

01/10/2012

**Date of final enrolment**

30/09/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Northern General Hospital**

Sheffield

United Kingdom

S5 7AU

## **Sponsor information**

**Organisation**

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

**Sponsor details**

c/o Erica Wallis

Research Department

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S10 2SE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/018hjpz25>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	25/10/2012		Yes	No
<a href="#">Results article</a>	results	23/07/2016		Yes	No
<a href="#">Results article</a>	results	01/11/2016		Yes	No
<a href="#">Other publications</a>	lessons learnt	01/11/2019	06/11/2019	Yes	No