

Randomised controlled trial comparing two treatment methods for symptomatic haemorrhoidal disease

Submission date 05/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/06/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/01/2020	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A randomised trial of stapled haemorrhoidopexy versus rubber band ligation in the treatment of circumferential symptomatic grade II haemorrhoids

Study objectives

Treatment with stapled haemorrhoidopexy produces better symptom control and less recurrent disease compared to rubber band ligation; both are considered to treat the disease in a similar mechanism of fixing the haemorrhoidal cushion without excising them.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Grampian Research Ethics Committee on the 11th August 2002 (ref: 01/0297).

Study design

Single centre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Circumferential grade II symptomatic haemorrhoids

Interventions

1. Rubber band ligation
2. Stapled haemorrhoidopexy

Both arms are treated as a one-off to begin with and then reviewed at six weeks. As per the protocol, If there is a recurrence of disease, a repeat treatment can be given. The rubber band ligation can be repeated up to four times at six-week intervals, before being declared failure of treatment. Similarly, the stapled haemorrhoidopexy will be repeated up to two more times before declared as failure of treatment.

Total follow-up is up to one year including 6-week and 26-week follow-ups in between.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Disease recurrence at six weeks and one year.

Key secondary outcome(s)

1. Symptom score (validated and published already)
2. Cleveland continence score
3. Quality of life score (36-item Short Form health survey [SF-36], EuroQoL instrument [EQ-5D] and Hospital Anxiety and Depression Scale [HAD] scores)

- 4. Cost effectiveness
- 5. Sphincter damage

All secondary outcomes were assessed at 6 weeks, 26 weeks and one year.

Completion date

02/04/2005

Eligibility

Key inclusion criteria

Circumferential grade II symptomatic haemorrhoids irrespective of age and gender.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Associated anaorctal sepsis
2. Associated colonic malignancy or inflammatory bowel disease
3. Associated anal sphincter pathology

Date of first enrolment

20/10/2002

Date of final enrolment

02/04/2005

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Ward 50

Aberdeen

United Kingdom

AB25 2ZN

Sponsor information

Organisation

University of Aberdeen Medicines Assessment Research Unit (MARU)

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Ethicon Endo-Surgery (Europe) GmbH (Germany)

Results and Publications

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?
Results article	results	01/06/2010		Yes	No