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Randomised controlled trial comparing two treatment methods for symptomatic haemorrhoidal disease

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Disease recurrence at six weeks and one year.

Secondary outcome measures
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.

Overall study start date
20/10/2002

Completion date
02/04/2005

Eligibility

Key inclusion criteria
Circumferential grade II symptomatic haemorrhoids irrespective of age and gender.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
60

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
Scotland

United Kingdom

Study participating centre
Ward 50
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
University of Aberdeen Medicines Assessment Research Unit (MARU)

Sponsor details
c/o Mr MA Loudon and Mr AJM Watson
Grampian Hospitals NHS Trust
Aberdeen Royal Infirmary
Ward 50
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsgrampian.org

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ethicon Endo-Surgery (Europe) GmbH (Germany)

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?
Results article	results	01/06/2010		Yes	No