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# Randomised controlled trial comparing two treatment methods for symptomatic haemorrhoidal disease

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr Malcolm Loudon

**Contact details**
Ward 50
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
United Kingdom
AB25 2ZN

## 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
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZN

**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 |