

Ligasure haemorrhoidectomy versus conventional diathermy haemorrhoidectomy: one year follow up

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/10/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

N0436125589

Study information

Scientific Title

Study objectives

To compare the long-term results of ligasure with conventional diathermy haemorrhoidectomy in the treatment of symptomatic grade III and IV haemorrhoids.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

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

Health condition(s) or problem(s) studied

Haemorrhoidectomy

Interventions

Randomised controlled trial; Before-after trial. Random Allocation to:

1. Ligasure
2. Conventional Treatment

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Anorectal physiology and endoanal ultrasound were not included in the original trial so there is no data for direct comparison. However this information is important to correlate patient symptomatology with quantitative assessment of sphincter anatomy and function.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2003

Completion date

01/09/2003

Eligibility

Key inclusion criteria

All 40 previous participants of the Ligasure versus conventional diathermy study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/03/2003

Date of final enrolment

01/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Unit of Surgeons
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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	01/07/2005		Yes	No