

Randomised trial of surgery versus fibroid embolisation in the treatment of clinically significant menorrhagia

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|--------------------------|---------------------------------|--|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 30/09/2004 | Stopped | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 30/09/2004 | Stopped | <input type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 27/05/2010 | Urological and Genital Diseases | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0084120683

Study information

Scientific Title

Study objectives

Is fibroid embolisation as effective as surgery in the treatment of anaemia due to menorrhagia caused by fibroids?

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Menorrhagia

Interventions

Please note that as of 27/05/10 the status of this trial was changed to "stopped" as the trial was never started.

Randomised controlled study

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. End point - one year post treatment or hysterectomy in the embolisation group
2. Outcome measures - Quality of life, haematocrit, length of hospital stay, time to return to work, patient satisfaction, complications, costs

Key secondary outcome(s)

Not provided at time of registration

Completion date

28/02/2004

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

One hundred women with clinical anaemia due to menorrhagia caused by fibroids randomised to most appropriate surgery or embolisation.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/06/1999

Date of final enrolment

28/02/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The Academic Department of Obstetrics & Gynaecology

Hull

United Kingdom

HU3 2JZ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Research organisation

Funder Name

The North and South Bank Research and Development Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration