

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/1999

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

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre
The Academic Department of Obstetrics & Gynaecology
Hull
United Kingdom
HU3 2JZ

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
Research organisation

Funder Name
The North and South Bank Research and Development Consortium (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