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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/05/2010	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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