

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/05/2010	<b>Condition category</b> 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

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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