

Randomised trial of gelatin versus embospheres for uterine fibroid embolisation

Submission date 27/08/2008	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/09/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/09/2017	Condition category Cancer	<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
CZB/4/683

Study information

Scientific Title
Uterine artery embolisation for symptomatic fibroids: Comparison of gelatin sponge with embospheres as an embolic agent - a randomised controlled trial (GEM trial)

Acronym

GEM

Study objectives

Randomised controlled trial (RCT) comparing gelatin sponge with Embosphere® for uterine artery embolisation for women with uterine fibroids.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Glasgow Ethics Committee approval pending as of 11/02/2009

Study design

Open randomised equivalence trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Uterine fibroids

Interventions

Uterine artery embolisation with either gelatin sponge or Embosphere®.

Total duration of follow-up: 12 months

Intervention Type

Procedure/Surgery

Primary outcome(s)

Degree of fibroid infarction using contrast enhanced MRI, assessed at baseline, 1, 6 and 12 months

Key secondary outcome(s)

Assessed at baseline, 1, 6 and 12 months:

1. Ovarian function and reserve
2. Quality of life, assessed by Euroqol, Uterine Fibroid Symptom and Quality of Life questionnaire (UFSQoL)
3. Symptom relief, assessed by a linear 11-point score -5 through zero to + 5
4. Reintervention rate

Completion date

01/12/2011

Eligibility**Key inclusion criteria**

1. Patients referred for uterine artery embolisation

Added 13/02/2009:

2. Females aged 18 - 55 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Pregnant
2. Allergy to radiographic contrast media
3. Unable to tolerate magnetic resonance imaging (MRI) scan

Date of first enrolment

01/01/2010

Date of final enrolment

01/12/2011

Locations

Countries of recruitment

United Kingdom

Study participating centre

Gartnavel General Hospital

Glasgow

United Kingdom

G12 OYN

Sponsor information

Organisation

Greater Glasgow and Clyde NHS Board (UK)

ROR

<https://ror.org/05kdz4d87>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) - applied for funding, not confirmed yet

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration