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Randomised trial of gelatin versus embospheres for uterine fibroid embolisation

Submission date 27/08/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/09/2008	**Overall study status** Stopped	
Last Edited 20/09/2017	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

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)

Sponsor details
c/o Melissa McBride
R&D
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Sponsor type
Hospital/treatment centre

Website
http://www.nhsgg.org.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

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