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Multicentre randomised controlled trial comparing uterine artery embolisation with surgical treatment for uterine fibroids

Submission date 08/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/03/2006	**Overall study status** Completed	
Last Edited 04/02/2016	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Uterine fibroids are non-cancerous growths that form on the wall of a woman's womb (uterus). Several different procedures can be used to treat fibroids. Surgical treatments include myomectomy (removal of the fibroids from the wall of the womb) and hysterectomy (removal of the womb). Non-surgical procedures include uterine artery embolisation (UAE), which involves blocking the blood vessels that supply the fibroids, causing them to shrink. The aim of this study is to compare UAE with surgery (hysterectomy and myomectomy) in patients with fibroids who would ordinarily receive surgical treatment.

Who can participate?
Women with symptomatic fibroids who would normally undergo surgery for treatment.

What does the study involve?
Participants are randomly allocated to be treated with either UAE or surgery. Their quality of life is assessed 12 months later.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Gartnavel General Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2000 to September 2010

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Jonathan Moss
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
czh/4/1

Study information

Scientific Title
Multicentre randomised controlled trial comparing uterine artery embolisation with surgical treatment for uterine fibroids

Acronym
REST

Study objectives
Compare results of embolisation with surgery for uterine fibroids.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Multicentre Reseach Ethics Committee (MREC) of Edinburgh, 11/05/2000, ref: MREC/00/0/29

Study design
Open randomised controlled trial allocation 2:1 in favour of new intervention

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Uterine fibroids

Interventions
Uterine artery embolisation versus surgical treatment

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The 36-item Short Form health survey (SF-36) quality of life questionnaire.

Secondary outcome measures
1. Symptom scores
2. Complications
3. Return to lifestyle events
4. Pain scores
5. Cost analysis

Overall study start date
01/11/2000

Completion date
01/09/2010

Eligibility

Key inclusion criteria
Women with symptomatic fibroid who would normally undergo surgery for treatment.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Pregnancy
2. Unable to image with magnetic resonance imaging (MRI)
3. Fibroid size less than 2 cm
4. Subserosal fibroid on a stalk

Date of first enrolment
01/11/2000

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
United Kingdom

Study participating centre
Gartnavel General Hospital
Glasgow
United Kingdom
G12 OYN

Sponsor information

Organisation
Greater Glasgow Health Board (North Glasgow University Hospitals Division) (UK)

Sponsor details

300 Balgray Hill Road
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United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.ngt.org

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) (ref: CZH/4/1)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2007		Yes	No
Results article	results	01/07/2010		Yes	No
Results article	5-year results	01/07/2011		Yes	No