ISRCTN67347987 https://doi.org/10.1186/ISRCTN67347987

Diffusion Weighted MRI and MRI spectroscopy in the assessment of Uterine Artery Embolisation (UAE): a comparison between a temporary (GelFoam) and a permanent (Embospheres) embolic agent

Submission date
10/10/2012

Recruitment status
No longer recruiting

Registration date
15/11/2012

Overall study status
Completed

Last Edited
22/11/2019

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The main purpose of this study is to investigate whether new specialised Magnetic Resonance Imaging (MRI) scans spectroscopy and diffusion weighted imaging - can detect early changes in uterine fibroids after uterine artery embolisation (UAE) (is a procedure where an radiologist uses a catheter to deliver small particles that block the blood supply to the uterine fibroids). We hope to investigate the effect of UAE using two different materials using these two specialised MRI scans. UAE is a relatively new procedure for women with troublesome fibroids. Although UAE is a successful treatment in the majority of women in about 10-15% of cases we do not succeed in blocking off the blood supply to the fibroid completely. There are several different products (embolic agents) on the market which we use to block off the arteries to the womb. We do not know which the best is or whether they are all equal. They vary in cost and it is possible that one may carry advantages over another in terms of success rate in killing off the fibroid and also minimising the damage to the ovaries. Both the products we are using are established embolic agents used for embolising uterine fibroids both in the UK and other countries.
New MRI sequences may be able to help answer the questions as to how the fibroids behave immediately after they have been treated.

Who can participate?
20 patients referred for routine uterine artery embolisation will be invited to participate.

What does the study involve?
Much of what is involved is simply part of the UAE procedure. The whole study lasts 7 months. Participants will be randomly allocated one of the study agents. This process is carried out by computer and there is a 50% chance of receiving either product. The first out patient visit will last approximately 30 minutes at the hospital and a research nurse will ask questions about health and fibroid related problems. At this point participants will be invited to join the study.

Participants are free to pull out at any time. At some point prior to the UAE, ideally in days 2-5 of the menstrual cycle participants will be invited to give a blood sample to measure oestrogen and other hormone levels, which give a measure of ovarian function and reserve. The second visit involves an MRI scan. This is normal practice and the only extra thing is two additional sequences on the scanner, lasting around 30 minutes. The third visit will be for the UAE procedure, which will be carried out using one or other of the study embolic agents. The following day we will perform an extra MRI scan and take another blood test. We will be seeing participants in the out-patient clinic at 1, 6 months. We will repeat the same blood tests at each visit. At approximately 6 months following the UAE procedure we will repeat the MRI scan, this is normal practice (except for the additional two sequences). This helps us assess the fibroids more accurately.

What are the benefits and risks of taking part ?
There will be no immediate direct benefit to those taking part. But there should be benefits to future patients having uterine artery embolisation and to the NHS because the results of the study are likely increase knowledge of the effects of embolisation and comparison of the two agents will provide information on cost effectiveness of embolic agents. There are no specific risks to participating in this study. However, additional time in the MRI scanner can lead to feelings of claustrophobia. The blood tests although straightforward do involve some minor discomfort with the risk of some minor bruising.

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

When is the study starting and how long is it expected to run for?
January 2011 to August 2012

Who is funding the research?
British Society of Interventional Radiology (UK)

Who is the main contact?
Professor Jon. G. Moss
Jon.moss@ggc.scot.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Jonathon Moss

Contact details
Dept of radiology
Gartnavel general Hospital
Glasgow
United Kingdom
G12 0YN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2, 17th November 2010

Study information

Scientific Title
Diffusion Weighted MRI and MRI spectroscopy in the assessment of Uterine Artery Embolisation (UAE): a comparison between a temporary (GelFoam) and a permanent (Embospheres) embolic agent - Randomised pilot study

Study objectives
To demonstrate whether diffusion weighted MRI and MRI Spectroscopy can detect differences between two different embolic agents (GelFoam and Embospheres) following UAE. Is there any difference between these two agents regarding any adverse effects on ovarian function and reserve?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee ref 09/S0703/108 , 13th October 2009
Substantial amendment approved 14th December 2010

Study design
Randomised pilot study

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
Symptomatic uterine fibroids

Interventions
Patients referred for routine UAE will be randomised to receive one of two embolic agents. Diffusion weighted MRI and spectroscopy sequences will be carried out at baseline, 24hrs and 6months.

Uterine artery embolisation, contrast enhanced magnetic resonance imaging, spectroscopy, diffusion weighted magnetic resonance imaging, venous blood samples.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Diffusion weighted magnetic resonance imaging and spectroscopy of fibroids pre-embolisation and at 24hrs and 6 months post embolisation to detect changes in the fibroid uterus in both arms (Gelfoam and Embospheres)

Secondary outcome measures
1. Ovarian function and ovarian follicle reserve at baseline, 24hrs, 1 month and 6 months (Luteinising hormone, Follicle stimulating hormone, Anti-mullerian hormone)
2. Cost-effectiveness comparison Gelfoam, Embospheres

Overall study start date
21/01/2011

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. Symptomatic fibroids
2. MRI shows fibroids are greater than 2cm in diameter
3. Willing to be randomised

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
20

Total final enrolment

Key exclusion criteria
1. Severe allergy to radiographic contrast
2. Active infection
3. Contra-indication or unable to tolerate MRI
4. Unable or unwilling to comply with protocol

Date of first enrolment
21/01/2011

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Gartnavel General Hospital
Department of Radiology
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
Tennent Institute
Western Infirmary
1st Floor 38 Church Street
Glasgow
Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
British Society of Interventional Radiology (UK)

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	01/01/2019	22/11/2019	Yes	No
HRA research summary			28/06/2023	No	No