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Randomised controlled trial of Particles used in Uterine fibRoid Embolisation (PURE)

Submission date
02/02/2013

Recruitment status
No longer recruiting

Registration date
21/02/2013

Overall study status
Completed

Last Edited
31/10/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Uterine fibroids are a common gynaecological condition affecting women of reproductive age. Approximately half of women with fibroids experience symptoms including heavy menstrual bleeding, abdominal pain and pressure, all of which can impact on quality of life. The choice of treatment is between surgical removal of the fibroids / womb (myomectomy or hysterectomy) or a minimally invasive treatment called uterine artery embolisation (UAE).
UAE is a minimally invasive interventional radiology procedure which blocks the blood vessels supplying the uterus. These vessels are accessed via arteries in the groin and using a small tube (angiographic catheter) to inject biodegradable particles into the arteries supplying the uterus. The fibroids fail to regain a blood supply and undergo necrosis (cell death).
Many different particulate agents are in use for UAE. The two agents in this study are Contour non-spherical polyvinyl alcohol (PVA) and Embozenes (Polyzene coated hydrogel microspheres). Both the embolic agents are safe and approved for use in uterine artery embolisation.
Non-spherical polyvinyl alcohol (PVA) has been used for more than two decades and is inexpensive. However this embolic agent has a tendency to clump and can block larger calibre vessels than the specified diameter of the particle. New calibrated particles have been developed which do not clump with claims that this is advantageous. The calibrated particles have a cost implication and yet there is no current evidence to back the manufacturers and physicians claims that they are superior to non-spherical PVA. Both the agents are tiny inert plastic beads that are designed to block blood flow within arteries. Both embolic agents contain particles that are of a similar size range (350 to 1100 micrometres).
As well as being minimally invasive, one of the advantages of UAE is its reduced cost compared with surgery. The results of the two particulate agents will be assessed comparing the improvement in the quality of life using validated QOL forms and fibroid infarction rates using routine contrast enhanced MRI scans at 6 months.

Who can participate?
Female patients aged 18-55 years with symptomatic fibroids admitted for uterine artery embolisation

What does the study involve?
Comparison of two embolic agents:

1. Contour Non-spherical polyvinyl alcohol (PVA). Boston Scientific, USA. CE 0197
2. Embozene Microspheres (calibrated hydrogel microspheres with polyzene coating). CeloNova Biosciences, USA. CE 0086
Aside from the difference in embolic particles used to block the arteries to the womb the rest of the clinical treatment is identical. Participants will be randomised to one embolic agent or the other.
The study processes: interventional procedure; clinical care; follow-up; and post procedure MRI scans, are already standard practice in our institution and identical between the two study groups.

What are the possible benefits and risks of participating?
There are no specific benefits to study participants. The treatment given to patients in either treatment arm of the study is equally effective in current medical practice. Patients will have the same care during the procedure and close follow-up whether entered into the study or not.
The substances injected are embolic agents consisting of inert plastic / polymer-based microspheres. Both embolic agents are CE marked and classed for commercial use for embolisation in uterine artery embolisation. There are procedural risks that are related to the angiographic study and vascular interventional techniques required to access the uterine arteries but are not specific to the embolic agents in this study. The risk benefit ratio of performing UAE has been well established and UAE has an excellent safety profile.

Where is the study run from?
This is a single centre study based at St Georges Healthcare NHS Trust in London.

When is the study starting and how long is it expected to run for?
The start date is January 2013 and the study will last approximately 2 years until the final participant completes 6 months follow-up.

Who is funding the study?
St Georges Healthcare NHS Trust, London, UK

Who is the main contact?
Dr Raj Das (Study coordinator / Principal Investigator)
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Contact information

Type(s)
Scientific

Contact name
Prof Anna-Maria Belli

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NRES study 12/LO/1581. Sponsor reference number: 12.0126. Study Protocol V1.1

Study information

Scientific Title
Randomised controlled trial of Particles used in Uterine fibRoid Embolisation (PURE): Non-spherical polyvinyl alcohol versus calibrated hydrogel microspheres with polyzene coating

Acronym
PURE

Study objectives
PURE study is designed to detect differences in outcome (clinical and radiological) between uterine artery embolisation performed with non-spherical polyvinyl alcohol (Contour PVA) versus calibrated hydrogel microspheres with polyzene coating (Embozenes)

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Dulwich, London, 11/01/2013, ref: 12/LO/1581

Study design
Prospective single blinded randomised controlled 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 below to request a patient information sheet

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

Interventions
Uterine artery embolisation performed using either:
1. Contour Non-spherical polyvinyl alcohol (PVA), Boston Scientific, USA. CE 0197

OR

2. Embozene Microspheres (calibrated hydrogel microspheres with polyzene coating), CeloNova Biosciences, USA. CE 0086

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To confirm whether microsphere embolic particles (Embozenes) improve patients quality of life compared with the standard agent of non-spherical PVA (Contour PVA). This is measured using the validated Uterine Fibroid Symptom and Health-related Quality of Life questionnaire (UFS-QOL).

Secondary outcome measures
1. Contrast-enhanced MRI performed before and 6 months after UAE
2. Percentage Fibroid infarction - total fibroid burden and dominant fibroid infarction
3. Uterine and dominant fibroid volume reductions

Overall study start date
01/01/2013

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Symptomatic fibroids admitted for uterine artery embolisation
2. Female participants aged 18-55 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Target number of participants
80

Total final enrolment
84

Key exclusion criteria
1. Recent or ongoing pelvic inflammatory disease
2. Severe radiographic contrast medium allergy.
3. Significant adenomyosis, as identified by transvaginal ultrasound or MRI. Concurrent adenomyosis where fibroids are believed to the predominant cause of symptoms will be eligible.
4. Positive pregnancy test
5. Refusal to accept hysterectomy, in the event of an intra-operative complication.
6. Suspected malignancy
7. Age< 18
8. Unable to provide informed consent due to incapacity (as defined by Mental Capacity Act 2005 or Adults with Incapacity (Scotland) Act 2000.
9. A non English speaker where translation or interpretation facilities are insufficient to guarantee informed consent

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Radiology
London
United Kingdom
SW17 0QT

Sponsor information

Organisation
St George's Healthcare NHS Trust (UK)

Sponsor details
c/o Ms Nadia Azzouzi
St Georges Joint Research Office
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England
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SW17 0RE

Sponsor type
Hospital/treatment centre

Website
http://www.stgeorges.nhs.uk/

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Georges Healthcare NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/02/2022	31/10/2022	Yes	No
HRA research summary			28/06/2023	No	No