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Treating fibroids with either embolisation or myomectomy to measure the effect on quality of life among women wishing to avoid hysterectomy: the FEMME study

Submission date
02/03/2012

Recruitment status
No longer recruiting

Registration date
02/03/2012

Overall study status
Completed

Last Edited
22/12/2022

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Fibroids are the most common benign tumor in women and by the time they are 50 years old around four out of five women will have had a fibroid. Of the women who develop fibroids, around half will experience symptoms that will adversely affect their quality of life. These symptoms can be quite severe and may include severe abdominal pain, pain during intercourse, heavy and painful menstrual bleeding, and a constant feeling of needing to go to the toilet. On top of this, some women with fibroids may experience difficulty in conceiving, and if they do conceive they are at a higher risk of miscarriage compared with women of the same age without fibroids. As many women are starting a family later in their life, fibroids are a growing problem. Treatments for fibroids are available and fall into two main types: drug and surgical. Women with symptomatic fibroids often respond poorly to drug treatments and many find the side effects of these hormonal preparations unacceptable. This means that drug treatments may only be given for a short time, usually to dampen down the most severe symptoms and to try and shrink the fibroid before it is surgically removed. In the NHS today there are currently three surgical treatments readily available for fibroids: hysterectomy, myomectomy, and uterine artery embolisation (UAE). There are many different types of hysterectomy but they all have in common the removal of the womb. Studies have shown that many women regard their womb as being integral to their femininity and sexuality, and so it is unsurprising that if asked what sort of treatment they would like to receive for their fibroids, the vast majority of women would like to receive a treatment that allows them to retain their uterus. With many hysterectomies being performed to treat benign conditions, this has led many women to question if they are losing their wombs unnecessarily. With numerous women now looking for an alternative to hysterectomy, myomectomy and UAE are growing in favour. During a myomectomy the fibroids are surgically removed but as much of the uterus as possible is preserved. Similarly, UAE, where a very thin hollow tube is used to deliver small beads which block the blood flowing to the fibroid, is also a womb-preserving procedure.

With both myomectomy and UAE having their own risks and potential side effects, many health care professionals are uncertain which is the best one to offer to women who wish to retain

their wombs. A few studies have compared UAE with myomectomy but these did not contain enough patients to give a definite result. This means that there is uncertainty as to what is the best treatment to offer to women with fibroids who want to retain their womb. This study aims to compare the changes in the quality of life women experience after their fibroids are treated with either UAE or myomectomy.

Who can participate?
Women aged over 18 years with symptomatic fibroids who do not wish to have a hysterectomy and are suitable for either treatment (myomectomy or embolisation).

What does the study involve?
Participants will be randomly allocated to have either a myomectomy or UAE. We will record how well the participants feel after two years and four years using questionnaires. We will also measure the changes in menstrual blood flow after each procedure as well examining if UAE and myomectomy change the level of ovarian hormones associated with fertility. Of course, there is a more direct method of measuring fertility, and we will record the outcome of any pregnancy that may occur in the women involved in the study. To measure the effectiveness of myomectomy and UAE, information on any follow-up procedures that women may have to undergo will also be collected.

What are the possible benefits and risks of participating?
You will not gain any individual benefit by taking part in the study but the study will provide valuable information to decide which treatment is best for future women suffering from fibroids. Myomectomy and UAE are both safe procedures and are in routine use within the NHS. Some studies have suggested that women who have a UAE recover from their operation more quickly than those who have a myomectomy, but may be more likely to have the need for more treatment in the future. On top of this, both myomectomy and UAE are associated with a range of complications. Although rare, there are risks for each procedure. For myomectomy the possible risks include: haemorrhage, injury to the uterus, damage to the nearby organs of the urinary system, formation of scar tissue (adhesions) within the uterus, infection, blood clots and eventual re-growth of fibroids. For UAE the possible risks include: damage to the uterus, bladder, vulva and ovaries, flu-like symptoms, pain, vaginal discharge and early menopause. The effect that myomectomy and UAE have on the chance of getting pregnant is unknown at present. In order to ensure that the tube delivering the beads is in the right place it will be guided there under x-ray imaging. Whilst any exposure to ionising radiation carries an increased risk of developing cancer, it is the size of this risk that is important. The lifetime risk of developing a fatal cancer following UAE is 1 in 3,330. This is similar to the lifetime risk of dying from an accident at work in the manufacturing industry, and a lot less than the lifetime risk of dying in a transportation accident in the UK (1 in 240). Your doctor will discuss the risks and discomforts of the allocated treatment and give you more details of what to do if you experience any side effects.

Where is the study run from?
Birmingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
February 2012 to December 2019

Who is funding the study?
NIHR Health Technology Assessment (HTA) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11877; HTA 08/53/22

Study information

Scientific Title
A randomised trial of treating Fibroids with either Embolisation or Myomectomy to Measure the Effect on quality of life among women wishing to avoid hysterectomy: the FEMME study

Acronym
FEMME

Study objectives
A fibroid is a common non-cancerous growth of the uterus (or womb). Many women have fibroids without knowing it and do not need treatment. Larger or multiple fibroids can cause abnormal vaginal bleeding, pain, abdominal discomfort or bloating, bladder problems and other symptoms. The surgical removal of the fibroid without removing the womb (myomectomy) is possible in some patients. Uterine artery embolisation (UAE) is a newer treatment, which works by blocking the blood supply to the fibroid and causing it to die and shrink over a period of several months.

UAE and myomectomy are safe, effective procedures, each with advantages and disadvantages. To control symptoms, the choice is currently very uncertain and doctors do not know which women will benefit most from either procedure.

Since the options are so different, requiring very different hospital stays, possibly with different effects on fertility, sexual function and recurrence of fibroids, it is important to compare the two procedures against each other.

The FEMME trial is a multicentre randomised trial comparing UAE with myomectomy for women with symptomatic fibroids wishing to retain their womb. 216 eligible women will be randomised in a 1:1 ratio to myomectomy or embolisation. Participants will be recruited from over 20 UK hospitals by gynaecologists and interventional radiologists. The primary outcome of quality of life will be assessed by use of a disease specific questionnaire at two years. Effectiveness will also be assessed at 6 months and 1 and 4 years after treatment. Secondary outcomes include effect on menstrual bleeding, pregnancy outcomes, further treatment and adverse events. Ovarian function will be assessed on a subgroup of women. Data on resource use will be collected to for an economic evaluation.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/085322
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/52977/PRO-08-53-22.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Coventry and Warwickshire, 15/06/2011, ref: 11/WM/0149

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Myomectomy, Surgical removal of fibroid via an excision(s)

Uterine Artery Embolisation (UAE) - introduction of an embolic agent which blocks the blood supply to the fibroid causing it to necrose

Follow Up Length: 48 month(s); Study Entry : Single Randomisation only

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current primary outcome measure as of 03/05/2019:
Quality of life assessed using the Uterine Fibroid Symptom and Quality of Life (UFS-QoL) tool. The health-related quality of life (HRQoL) domain will be the primary outcome, whilst the symptom domain will be a secondary outcome. The HRQoL score at two years of follow-up will be considered the primary timepoint.

Previous primary outcome measure:
The change in the quality of life experienced by women after they undergo UAE or myomectomy. This will be reported after two years and four years.

Key secondary outcome(s))
Current secondary outcome measures as of 03/05/2019:
1. Health-related quality of life assessed using the HRQoL domain from the UFS-QoL questionnaire at 6 months, 1 year and 4 years
2. Symptom severity assessed using the symptom severity domain from the UFS-QoL questionnaire at 6 months, 1, 2 and 4 years
3. EQ-5D-3L score assessed using the EuroQoL EQ-5D-3L questionnaire at 6 months, 1, 2 and 4 years
4. Health thermometer score assessed using the EuroQoL EQ-5D-3L questionnaire at 6 months, 1, 2 and 4 years
5. Menstrual blood loss – rates of amenorrhea and non-heavy bleeding assessed using the Pictorial Blood loss Assessment Chart (PBAC) at 6 months, 1, 2 and 4 years
6. Pregnancy outcomes – pregnancy (reported by the women in the first instance), live birth, miscarriage, stillbirth and termination assessed using a participant questionnaire over 2 and 4 years
7. Adverse events – all adverse outcomes considered to be related to the study protocol or intervention will be collected using clinical reports and participant questionnaire over 2 and 4 years
8. Participant responses to 'would you have your operation again?', assessed at 6 months, 1, 2 and 4 years
9. Participant responses to 'would you recommend operation to a friend?', assessed at 6 months, 1, 2 and 4 years
10. Length of hospital stay assessed using clinical reports over 2 and 4 years
11. Further treatment for incomplete removal or recurrence of symptoms, including hysterectomies, assessed using a participant questionnaire over two and four years
12. Ovarian reserve (AMH, FSH and LH levels) measured using blood samples at 6 weeks, 6 months and at 1 year

Previous secondary outcome measures:
1. Changes in the level of ovarian hormones after UAE or myomectomy
2. Changes in menstrual blood loss
3. Number of adverse events
4. Outcomes of any pregnancies that occur
5. Resource use and re-intervention rates will be collected to determine the cost-effectiveness of each procedure

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Women with symptomatic fibroids who do not wish to have a hysterectomy
2. Women considered suitable for either treatment (myomectomy or embolisation) and having no strong preference for a particular treatment
3. Clinical team uncertain as to which treatment is indicated
4. Written informed consent

Target Gender: Female; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
254

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 magnetic resonance imaging (MRI)
4. Concurrent adenomyosis where fibroids are believed to the predominant cause of symptoms will be eligible
5. Positive pregnancy test
6. Refusal to accept hysterectomy, in the event of an intra-operative complication
7. Refusal to accept surgery or embolisation as treatment option
8. Post-menopausal, as defined as greater than one year since previous menstrual period
9. Suspected malignancy
10. Age < 18
11. Current participation in double blind, placebo controlled trials of drugs or other surgical interventions for heavy menstrual bleeding or fibroids
12. Unable to provide informed consent due to incapacity (as defined by Mental Capacity Act 2005 or Adults with Incapacity (Scotland) Act 2000)
13. A non-English speaker where translation or interpretation facilities are insufficient to guarantee informed consent

Date of first enrolment
20/03/2012

Date of final enrolment
21/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Clinical Trials Unit
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Oxford University (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment (HTA) (UK) (08/53/22)

Results and Publications

Individual participant data (IPD) sharing plan
Requests by recognised external organisations to access the aggregated (and thus anonymised) datasets generated and analysed during the current trial should be sent to bctudatashare@contacts.bham.ac.uk. Requests for access to the aggregated datasets will be considered by the trial management group, the BCTU data sharing committee, and the Sponsors in line with standard data sharing practices for clinical trial data sets.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/07/2020	30/07/2020	Yes	No
Results article	cost-utility analysis results	01/05/2021	12/07/2021	Yes	No
Results article	Four-year follow-up	20/11/2021	09/12/2021	Yes	No
Results article	Cost-effectiveness	01/04/2022	19/04/2022	Yes	No
Results article	UFS-QOL at 4 years	13/12/2022	22/12/2022	Yes	No
Protocol article	protocol	29/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes