Safety and Efficacy of Embozene Microspheres for Uterine Fibroid Embolization compared to Embosphere for Symptomatic Relief from Uterine Fibroids

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The purpose of this clinical trial is to compare the safety and efficacy of Embozene® Microspheres for uterine fibroid embolization to Embosphere® for symptomatic relief from uterine fibroids.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Reproductive neoplasms female benign
Study type	Interventional

Summary

ID

NL-OMON36953

Source
ToetsingOnline

Brief title
UFE FDA Celonova

Condition

- Reproductive neoplasms female benign

Synonym
Uterine Fibroids

Research involving
Human

Sponsors and support

Primary sponsor: Celonova
Source(s) of monetary or material Support: Nl Celonova

Intervention

Keyword: embolic agent, embolization, fibroid, uterus

Outcome measures

Primary outcome

The primary effectiveness endpoint for this clinical trial is the proportion of subjects who have success, defined as 50% menstrual blood loss (MBL) reduction or less than 80 ml of MBL per cycle, evaluated by the alkaline hematin (AH) method, at 12 months.

The primary safety endpoint is the frequency of treatment emergent adverse events. There will be no hypothesis test for this endpoint because the rates of treatment emergent adverse events for embolization are very small, ranging from 0.04 - 0.2% in the literature.

Secondary outcome

There are three secondary effectiveness endpoints for this study: 1) The proportion of subjects with at least 90% infarct of the uterine fibroid at 6 months following treatment; 2) The impact of excessive bleeding of fibroids on quality of life will be assessed with the UFS QOL Questionnaire; And 3) The need for re-intervention with repeat embolization or other therapy for treatment failure assessed.

The results over time of the Uterine Fibroid Symptom & Health Related Quality

of Life questionnaire will be compared descriptively. The mean response to

pivotal summary evaluations will be presented for each treatment group, and

within treatment groups the results will be compared to baseline.

Study description

Background summary

Uterine fibroid embolization has become accepted as a leading minimally invasive treatment option for patients with
symptomatic uterine fibroids as reflected by the recent practice guideline by Spies et al. issued by the American
College of Obstetricians and Gynecologists1.
Embozene Microspheres have a narrow size distribution which provides good predictability with respect to arterial
transportation. Existing clinical data from Europe provide evidence that the use of Embozene Microspheres will improve the quality of life of patients to reduce symptoms associated with symptomatic fibroids, such as abnormal bleeding, pain, discomfort, and urinary problems.
Biosphere Medical*s Embospheres (K021397), the predicate device cleared for uterine fibroid embolization in 2002, is currently widely used for UFE procedures in the US. All studies of Embozene Microspheres, including in vitro and in vivo studies as well as clinical experiences in Europe provide evidence of noninferiority to Embospheres®.
Based on the proven performance in comparative bench studies, results of the FMEA, results reported in the published literature, and similarities and differences between Embozene Microspheres and similar devices, it is concluded that the benefits outweigh the risks of the Embozene Microspheres for uterine fibroid embolization. Furthermore, CeloNova Biosciences has conducted extensive design verification and validation testing to mitigate the risks associated
with this device. Results from clinical studies conducted in Europe support the benefits and risks associated with the device and provide evidence that the use of Embozene Microspheres will improve the quality of life of patients to reduce symptoms associated with symptomatic fibroids, such as abnormal bleeding, pain, discomfort, and urinary problems.
Embospheres®, the predicate device that was introduced into practice in the US in 2002,is widely used for UFE procedure in the US. All studies of Embozene Microspheres, including in vitro and in vivo studies as well as clinical experiences in Europe provide evidence of noninferiority to Embospheres®. Therefore, it is important to conduct this randomized study to demonstrate substantial equivalence in terms of the safety and efficacy of Embozene

Microspheres.

Study objective

The purpose of this clinical trial is to compare the safety and efficacy of Embozene® Microspheres for uterine fibroid embolization to Embosphere® for symptomatic relief from uterine fibroids.

Study design

Randomized, prospective, multi-center study of 225 female subjects age 30-50 years with symptoms from uterine fibroids. All subjects will be followed for a total of thirty-six (36) months following uterine fibroid embolization.

Intervention

All study participants will have the embolization procedure and the assignment of the patients to this particular therapeutic strategy falls within current practice of medicine.
The two treatment groups will have a 2:1 randomization scheme. Each site will enroll up to a maximum of 35 participants. At least 50% of the subjects will be from the United States.
The study regimen for each subject will consist of a screening/baseline phase (Visit 1), the procedure phase (Visit 2), and followup
phase (Visits 39).
The final verification of the patient medical condition can only be done during surgery. If, during If, during surgery, the physician decides that the patient is not a suitable candidate for UFE, she will not be included in the study and will receive a different treatment or no treatment for her condition, as discussed and agreed upon by both patient and physician prior to surgery.

Study burden and risks

The patient may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. Adequate information about all side effects will be provided to the patients by their radiologist and by the means of the patient information sheet. However, doctors do not know all the side effects that may occur and it is possible that additional side effects could occur other than those listed in the information sheet. Patients must tell the Principal Investigator about any side effects that they have while taking part in the study so they may properly monitor your health. If they experience a side effect or injury that may be related to this study or if they have an unscheduled visit
for medical care for any reason, they could contact the site by phone during a workday or at night or on weekends.
There is no guarantee that the patients will benefit from study participation.

The study treatment may result in an improvement of their symptoms, such as reduced bleeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Pre-menopausal women age 30-50 years at time of enrollment.
-Heavy menstrual bleeding with or without pain and bulk related symptoms

Exclusion criteria

Pregnant patient or intends to become.

Has HIV or other immunodeficient state
Already infarcted or calcified fibroids present.
Présence or suspicion of malignancy or infection

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-12-2012
Enrollment:	35
Type:	Anticipated

Ethics review

Approved WMO Date:	18-12-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-03-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41919.008.12