NEW SPERE: Uterine Fibroid Embolization (UFE) Study Using Newly Designed Embozene Microspheres

Published: 07-06-2006
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To provide clinical data on clinical efficacy to support embolisation of uterine fibroids using Embozene microsferes

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON29773

Source
ToetsingOnline

Brief title
UFE (Uterine Fibroid Embolization)

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
Uterine Fibroids

Research involving
Human

Sponsors and support

Primary sponsor: CeloNova BioSciences
Source(s) of monetary or material Support: tendele door industrie

Intervention

Keyword: Embolization, Embozene microspheres, Uterine Fibroids

Outcome measures

Primary outcome

Clinical succes(6 month)

1. Fibroid-related menorrhagia

2. Pain and discomfort

3. Overall health

Procedure safety:

4. Serious adverse events and complications

Secondary outcome

Morphology and outcome:

1. Size of uterus

2. Size of dominant fibroid

3. Hospitalization time

4. Time to return to normal activities

Study description

Background summary

Uterine artery embolisation for symptomatic fibroids is currently a standard routine procedure in our hospital. The embolic agent embozen microsferes is an alternetive for the currently used microsferes and the issue of the study is to do a post CE approval investigation on their use in the dedicated uterine fibroid population.

Study objective

To provide clinical data on clinical efficacy to support embolisation of uterine fibroids using Embozene microsferes

Study design

prospective non-randomized multi-centre study

Intervention

Embozene microsferes injection in the uterine arteries

Study burden and risks

No additional burden and risks correlated to the routine embolisation procedure

Contacts

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CeloNova BioSciences

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age between 25 and menopause
No intention to become pregnant within the two years following treatment
One or more uterine fibroids
Abnormal vaginal bleeding, abnormal menstrual pain or abnormal pelvic pain, as defined and document by the study CRF
Willing and able to sign the informed consent form

Exclusion criteria

Pregnant
Pelvic inflammatory disease
presence of one or more submucosal fibroids with more than 50% growth into the uterine cavity
Presence of pedunculated serosal fibroids as the dominant fibroid
Uterine fibroid with significant collateral feeding by vessels other than the uterine arteries
Adenomyosis as the dominant cause of the clinical symptoms
Endometrial neoplasia or pre-malignant hyperplasia
Any malignancy of the pelvic region
Any active infection of the pelvic region
Known allergy to IV contrast material
Blood coagulation disorder that would prohibit arterial puncture
Immunocompromized women
Post-menopausal or FSH> 40 mIU/mL
Hormonal treatment within the previous three month
Unwilling or unable to sign the informed consent formor to adhere to the study requirements, including completion of menstruyal bleeding records and follow-up visits

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2006
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2006
Application type:	First submission
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	NL11825.008.06