SAFE: Sequre for Adenomyosis and Fibroid Embolisation

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

Summary

ID

NL-OMON52676

Source
ToetsingOnline

Brief title
SAFE

Condition

- Reproductive neoplasms female benign
- Menstrual cycle and uterine bleeding disorders
- Vascular therapeutic procedures

Synonym
uterus fibroids and adenomyosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Guerbet,sa Guerbet nv

Intervention

Keyword: adenomyosis, embolisation, fibroid, microcatheter

Outcome measures

Primary outcome

QOL scores and MRI (the difference in volume) are the two main study

endpoints.

Secondary outcome

The secondary study endpoints are:

- Number vials / ml particles used (+ size)

- Number of protection coils used to avoid advert side branch non target

embolization

- Complications

- Imaging post-procedure at 3 month follow up MRI: % necrosis

(infarction 100% - 95- 100% or <95%)

- Procedure time

- Radiation exposure

- Peri-procedural pain (defined by analgesics administered)

Study description

Background summary

Uterine fibroid and adenomyosis embolization (UAE) is currently accepted as an alternative to uterine removal (hysterectomy) or to surgically remove fibroids (myomectomy) or adenomyosis in women who have symptoms such as: heavy menstrual bleeding, pain and other symptoms due to the presence of uterine fibroids or adenomyosis. Many women appreciate the results achieved with embolization: improvement or elimination of symptoms and reduction of the size of the

fibroids or adenomyosis while preserving the uterus and preserving fertility. Despite these good results, there is still a belief that fibroid embolization can be improved by using a different type of catheter, the 2.8F Sequre catheter. The feature of this catheter is that, due to its special size, it significantly reduces the risk of (partial) embolization of surrounding tissue.
The expected result of this study is to demonstrate that, using the 2.8F catheter, there is less unnecessary damage to the surrounding tissue compared to standard fibroid embolization.

Study objective

The aim of this research is to test the efficacy and safety of a new microcatheter 2.8F Sequre for treatment of uterine fibroids and/or adenomyosis with a standard embolization technique and to demonstrate the added value of this catheter, namely to reduce the possible risks compared to a standard catheter. The effectiveness of the catheter is examined. It is compared with the results of embolisations previously performed (retrospective status study) to eliminate the fibroids and/or adenomyosis. Also, the special size of the 2.8F Sequre catheter can help accelerate embolization with more embolate directly to the fibroid and/or adenomyosis and less embolate to surrounding tissue.

Study design

The Safe study is a single-center, prospective, cohort trial.

Intervention

Embolization of myomas and/or adenomyosis (UAE) with the microcatheter 2.8F, performed by experienced intervention radiologists.
Results are compared with retrospective status studies.

Study burden and risks

-MRI before embolization including questionnaire/ visit gynaecologist and blood sample (partly standard care)
-Fibroid or/and adenomyosis embolization
-MRI 3 months after embolization including questionnaire, visit radiologist (standard -care), and blood sample (not standard care)
- questionnaire contains question 'ethnicity'

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- premenopausal woman, age > 30yrs and <= 55yrs
- pure adenomyosis, uterine leiomyomata or adenomyosis dominancy with fibroids clinically
diagnosed and confirmed with MR imaging.
- symptoms e.g. heavy menstrual bleeding, pelvic pain, and bulk related symptoms.
- written informed consent.

Exclusion criteria

- fibroid >= 5 cm
- pregnancy
- seeking future pregnancy
- presence or suspicion of any gynaecologic malignancy
- presence or suspicion of any pelvic inflammatory disease
- pelvic congestion syndrome

- already infarcted / calcified leiomyomata
- bleeding disorder
- renal function disorder

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Sequre microcatheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-12-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-06-2022
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	NL74393.028.21