SYMPRES study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28362

Source
Nationaal Trial Register

Brief title
SYMPRES

Health condition

- Niche
- Cesarean section scar defect
- Gynaecological symptoms
- Laparoscopy

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Primary outcome is number of days of uterine blood loss between two menstruation, six months after randomisation, using avalidated blood loss calender to be filled in by the patient.

Secondary outcome

Secundary outcomes are gynaecological complaints such as heavy and/or painful uterine blood loss. Patient satisfaction andquality-of-life. Surgical outcomes, niche characteristics, re-interventions, extra hormonal treatment or surgical interventions ninemonths after randomization. Medical consultations and costs

Study description

Background summary

niche is a defect that can develop at the site a cesarean section scar. Approximately 60% of the women with aprevious cesarean section will develop such a niche. In 25% of the niches, a large symptomatic niche develops,with less than 3 mm of residual myometrium. This causes complaints such as abnormal uterine blood loss,dysmenorrhea, chronic pelvic pain and is related to infertility. Several hormonal therapies are available forgynecological complaints, such as oral anticonceptives, progesterone, intra-uterine device (IUD) with levenorgestrel. In case of failure of or contraindications to hormonal therapy, surgical intervention can be considered. Several innovative surgical therapies have been developed to treat niche-related symptoms, such as a laparoscopic niche resection. This treatment has been proven effective in the reduction of postmenstrual spotting and menstrual pain and its implementation in daily practice is increasing internationally. However,information on the effectiveness of this treatment in comparison with hormonal therapy in reduction of symptoms for women without a child wish, has not been studied yet. In the present study we aim to include women with a large niche and gynecological symptoms, randomize between a laparoscopic niche resection within 6 weeks(Intervention group) and hormonal therapy for nine months (Control group). After nine months, if the provided treatment is not effective enough, patients are eligible for additional surgical interventions.

Study objective

Laparoscopic niche-resection is a superior treatment for symptomatic niches compared with hormonal therapy.

Study design

- 3, 6 months
- follow up 12, 24 months

Intervention

Intervention: Laparoscopic niche resection performed within 6 weeks after randomization.
Control: Hormonal therapy (oral anticonceptives, progesterone, levenorgestrel IUD, GnRH

agonist) for nine months.

Contacts

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Eligibility criteria

Inclusion criteria

- women 18 years or older
- pre-menopausal (regular menstrual cyclus)
- large, symptomatic niche after caeserean section

Exclusion criteria

- Age <18 years
- Pregnancy
- Desire to become pregnant within one year
- Contraindications for general anesthesia,
- (Suspected) malignancy,
- Uterine of cervical polyps
- Submucosal fibroids,
- Atypical endometrial cells
- Cervical dysplasia,
- Cervical or pelvic infection,
- Hydrosalphinx

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-06-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54858
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9534
CCMO	NL73649.029.20
OMON	NL-OMON54858

Study results