

SYMPRES study

Gepubliceerd: 11-06-2021 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28362

Bron

NTR

Verkorte titel

SYMPRES

Aandoening

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

Ondersteuning

Primaire sponsor: VU medical center

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is number of days of uterine blood loss between two menstruation, six months after randomisation, using a validated blood loss calendar to be filled in by the

patient.

Toelichting onderzoek

Achtergrond van het onderzoek

niche is a defect that can develop at the site a cesarean section scar. Approximately 60% of the women with a previous 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 for gynecological complaints, such as oral contraceptives, progesterone, intra-uterine device (IUD) with levonorgestrel. 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Intervention: Laparoscopic niche resection performed within 6 weeks after randomization.
Control: Hormonal therapy (oral contraceptives, progesterone, levonorgestrel IUD, GnRH agonist) for nine months.

Contactpersonen

Publiek

Amsterdam UMC
J.A.F Huirne

020-5663754

Wetenschappelijk

Amsterdam UMC
J.A.F Huirne

020-5663754

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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,
- Hydrosalpinx

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	11-06-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	11-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54858
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten