

# SYMPRES study

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON28362

### Bron

Nationaal Trial Register

### 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 validated blood loss calender 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 or 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:	Actieve controle groep

## 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**

<b>Register</b>	<b>ID</b>
NTR-new	NL9534
CCMO	NL73649.029.20
OMON	NL-OMON54858

## **Resultaten**