

LAPRESS study

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A niche is a defect that can develop at the site of a caesarean section scar. A niche can cause complaints of abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain and is related to infertility. Several innovative surgical therapies have been...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28650

Bron

NTR

Verkorte titel

LAPRESS study

Aandoening

- Niche
- Cesarean section scar defect
- Secondary subfertility
- Laparoscopy

Ondersteuning

Primaire sponsor: VU medical center

Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time to ongoing pregnancy, defined as an intrauterine pregnancy with a fetal heart rate at 12

weeks gestation.

Toelichting onderzoek

Achtergrond van het onderzoek

A niche is a defect that can develop at the site a caesarean section scar. A niche can cause complaints of abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain and is related to infertility. Several innovative surgical therapies have been developed to treat niche related symptoms. A laparoscopic resection of the niche is preferred in a large (residual myometrium $\leq 3\text{mm}$) symptomatic niche. Reduction of symptoms and promising reproductive outcomes at a low complication rate have been reported in a few case series and cohort studies.

Objective of the study:

The aim of the study is to evaluate the effect of a laparoscopic niche resection in patients with secondary unexplained subfertility or failed IVF in comparison to expectant management on fertility, pregnancy outcome and postmenstrual spotting. Cost-effectiveness analysis will be executed alongside the study.

Doel van het onderzoek

A niche is a defect that can develop at the site a caesarean section scar. A niche can cause complaints of abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain and is related to infertility. Several innovative surgical therapies have been developed to treat niche related symptoms. A laparoscopic resection of the niche is preferred in a large (residual myometrium $< 3\text{mm}$) symptomatic niche. Reduction of symptoms and promising reproductive outcomes at a low complication rate have been reported in a few case series and cohort studies.

Onderzoeksopzet

- 3, 6, 12 months
- follow up during pregnancy
- follow-up: 2 years

Onderzoeksproduct en/of interventie

Laparoscopic niche resection, contraceptives during the first 6 months to enable healing of the uterine scar before a pregnancy is allowed, thereafter fertility therapies are allowed if needed, according to the local protocol.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women (>18 years) with the presence of a large niche and secondary unexplained subfertility, failed IVF, or with problems during their fertility therapy, such as intrauterine accumulation of fluid and/ or difficulties during the introduction of the ET of IU catheter will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pregnancy, age < 18 years, contraindications for general anaesthesia, a (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:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-04-2017
Aantal proefpersonen:	200
Type:	Onbekend

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50195
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6350
NTR-old	NTR6534
CCMO	NL57660.029.16
OMON	NL-OMON50195

Resultaten