

Observational prospective cohort study of the niche with a long term follow up.

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A niche is a defect that can be seen at the site of a uterine caesarean section scar. A niche is associated with gynaecological symptoms (abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain) and is related to infertility. Several hormonal...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20181

Bron

NTR

Verkorte titel

Niche cohort study

Aandoening

Niche

Caesarean scar defect.

Ondersteuning

Primaire sponsor: Vu medical center

Overige ondersteuning: = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effect on of various therapies or non-therapy on the main symptom or time to pregnancy

in case of no symptoms.

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 hormonal and surgical therapies have been developed to treat niche related symptoms. These include oral contraceptive pills or Mirena IUD, laparoscopic niche resection, hysteroscopic niche resection of a hysterectomy. In case of secondary infertility problems) and a large niche (residual myometrium $\leq 3\text{mm}$) a laparoscopic niche resection may be offered. Reduction of symptoms and promising reproductive outcomes at a low complication rate have been reported in a few case series and cohort studies. And the additional effect of a hysteroscopic niche resection on spotting has been proven in a randomised controlled trial.

Additional, although hardly studied, hormonal therapies are mostly offered as first line therapy in case of niche related symptoms. There is also very limited evidence on the effect of expectant management on reproductive outcomes in case of observed niches in women who are willing to conceive.

Objectives: The aim of the study is to evaluate the effect of all applied types of interventions including expectant management on niche related symptoms and reproductive outcomes in a prospective way with a long term follow-up.

Doel van het onderzoek

A niche is a defect that can be seen at the site a uterine caesarean section scar. A niche is associated with gynaecological symptoms (abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain) and is related to infertility. Several hormonal and surgical therapies have been developed to treat niche related symptoms. These include oral contraceptive pills or Mirena IUD, laparoscopic niche resection, hysteroscopic niche resection of a hysterectomy. In case of secondary infertility problems) and a large niche (residual myometrium $\geq 3\text{mm}$) a laparoscopic niche resection may be offered. Reduction of symptoms and promising reproductive outcomes at a low complication rate have been reported in a few case series and cohort studies. And the additional effect of a hysteroscopic niche resection on spotting has been proven in a randomised controlled trial. Since then both laparoscopic and

hysteroscopic niche resection have been implemented in daily practise. However given the limited numbers of studied cases in literature it is important to continue the evaluation of these therapies on symptoms and reproductive outcomes. Additional, although hardly studied, hormonal therapies are mostly offered as first line therapy in case of niche related symptoms. There is also very limited evidence on the effect of expectant management on reproductive outcomes in case of observed niches in women who are willing to conceive.

Onderzoeksopzet

: 3, 6 and 12 months, 24 months and 3 years after inclusion into the study

Onderzoeksproduct en/of interventie

The aim of the study is to evaluate the effect of all applied types of interventions including expectant management on niche related symptoms and reproductive outcomes in a prospective way with long term follow-up.

The study will be a large prospective cohort study with five subgroups (interventions/exposures)

- 1) Hormonal therapy this may be estrogens/progesterone combined contraceptive pills, progesterone only contraceptives (pills, implanon or Mirena IUD)
- 2) Hysteroscopic niche resection
- 3) Laparoscopic niche resection
- 4) Hysterectomy
- 5) Expectant management without the use of hormones.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women (>18 years) with the presence of a niche identified by TV sonography with a minimum depth of 2mm. Women may have or may not have symptoms (abnormal uterine blood loss, dysmenorrhea, chronic pelvic pain, subfertility) . Women may or may not have a desire to conceive.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age < 18 years or not able to understand Dutch or not able to complete questionnaires.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	18-12-2017
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6844
NTR-old	NTR7022
Ander register	: VUmc_2017-2539

Resultaten