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

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON20181

**Source**
NTR

**Brief title**
Niche cohort study

**Health condition**

Niche
Caesarean scar defect.

### Sponsors and support

**Primary sponsor:** Vu medical center
**Source(s) of monetary or material Support:** = initiator = sponsor

### Intervention

### Outcome measures

#### Primary outcome

The effect on of various therapies or non-therapy on the main symptom or time to pregnancy in case of no symptoms.

#### Secondary outcome

days of postmenstrual spotting, dysmenorrhoe (VAS), chronic pelvic pain (VAS), time to conceive, time to ongoing pregnancy, pregnancy outcomes, niche characteristics by ultrasound, patients satisfaction and quality of life (SF36), complications, surgical complications, additional interventions.

# Study description

### Background summary

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 ≤3mm) 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.

### Study objective

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 ¡Ü3mm) 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.

**Study design**

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

**Intervention**

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 18-12-2017 |
| Enrollment: | 250 |
| Type: | Anticipated |

## Ethics review

Not applicable
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL6844 |
| NTR-old | NTR7022 |
| Other | : VUmc_2017-2539 |

## Study results