

# LAPRESS study

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Other
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28650

### Source

NTR

### Brief title

LAPRESS study

### Health condition

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

## Sponsors and support

**Primary sponsor:** VU medical center

**Source(s) of monetary or material Support:** None.

## Intervention

## Outcome measures

### Primary outcome

Time to ongoing pregnancy, defined as a intrauterine pregnancy with a fetal heartrate at 12 weeks gestation.

### Secondary outcome

Fertility and pregnancy outcomes, satisfaction and quality of life, surgical outcomes (intervention group), additional interventions, niche characteristics.

Economic evaluation: direct and indirect costs will be executed from a social perspective.

## 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 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.

### Study objective

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.

### Study design

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

### Intervention

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.

## Contacts

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## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-04-2017
Enrollment:	200
Type:	Unknown

## Ethics review

Not applicable	
Application type:	Not applicable

## Study registrations

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

ID: 50195  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

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

## Study results