LAPRESS study

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28650

Source
Nationaal Trial Register

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 ≤3mm) 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 <3mm) 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 of cervical polyps, submucosal fibroids, atypical endometrial cells, cervical dysplasia, cervical or pelvic infection, hydrosalphinx.

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