The effectiveness of laparoscopic niche resection versus expectant management in patients with secondary subfertility and a large uterine caesarean scar defect (niche) on reproductive outcomes, a randomised controlled trial.

Published: 16-08-2017
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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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON50195

Source
ToetsingOnline

Brief title
LAPRESSstudy

Condition

- Sexual function and fertility disorders

Synonym
CS scar defect, Isthmocele

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Geen.

Intervention

Keyword: Cesarean section scar defect, Laparoscopy, Niche, Secondary subfertility

Outcome measures

Primary outcome

Primary outcome: time to ongoing pregnancy, defined as a intrauterine pregnancy with a fetal heartrate at 12 weeks gestation.

Secondary outcome

Secondary outcomes: 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

In the recent years the number of caesarens has increased significantly. A niche is a defect that can develop at the site of the 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 niche resection of the niche is an standad treatment in women with a large symptomatic niche (residual myomterium <3mm). Reduction of symptoms and promising reproductive outcomes at low complication rate have been reported in a few case series and cohort studies.

Study objective

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 design

The study is a multicentre randomised controlled trial. Patients will be randomly allocated to laparoscopic niche resection or expectant management for 9 months.

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.

Study burden and risks

Patients will be informed about the procedure en will be informed that at this moment there is no evidence about the effectiveness of the procedure. The procedure will be in a research setting. The risks of laparoscopy include perforation, infection or bleeding, and very rarely a defect and / or perforation of the bladder or bowel can occur. Therefore, this procedure is performed only by gynecologists with enough experience (> 30 previous laparoscopic resections niche).
In a previous cohort study the procedure is performed 101 patients, a low complication rate is reported.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women with the presence of a large niche after CS failed IVF or secondary unexplained subfertility or problems during their fertility therapy, such as intrauterine accumulation of fluid and/ or difficulties during the introduction of the ET of IU catheter and not meeting any of the exclusion criteria are eligible to be randomised.
Women with a large niche and a wish to conceive in the near future are also eligble to participate in the study.

Exclusion criteria

Pregnancy, age < 18 years
contraindications for general anaesthesia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2020
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28650
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL57660.029.16
OMON	NL-OMON28650