The costeffectiveness of double layer closure of the caesarean (uterine) scar in the prevention of gynaecological symptoms in relation to niche development.

Published: 10-12-2015
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Primary objective: to study the (cost) effectiveness of double layer closure of the uterine scar after a caesarean delivery, in comparison to single layer closure, in the prevention of niche development and related menstrual spotting.Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON47638

Source
ToetsingOnline

Brief title
2Close study

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
CS scar defect, Isthmocele

Research involving
Human

Sponsors and support

Primary sponsor: VUmc Gynaecologie
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Abnormal uterine bleeding, Caesarean section scar defect, Double layer closure, Istmocele

Outcome measures

Primary outcome

Primary outcome: post- and intermenstrual spotting 9 months after

randomization.

Secondary outcome

Secondary outcome: menstrual pattern (score card) and dysmenorhoe (VAS),

Quality of life (SF36 & EQ-5D-5L), societal reintegration (PROMIS), sexual

function (FSFI), Niche (characteristics), complications, surgery time and

costs, % of ongoing pregnancies, life birth rate and time to conceive in women

willing to conceive.

Study description

Background summary

Double layer compared to single layer closure of the uterus after a caesarean section (CS) leads to a thicker myometrial layer at the site of the CS scar (residual myometrium) and possibly decreases the development of niches. A niche is a CS defect at the site of the uterine scar and is associated with gynaecological symptoms including postmenstrual spotting (OR 3.1 (1.5 - 6.3)). It is also associated with failure of trail of labour after CS and possibly with subfertility. In the Netherlands single layer closure of the uterus is performed by 92% of the gynaecologists.

Hypothesis: Double layer closure of the uterine scar using unlocked continuous

running sutures reduces menstrual disorders and pain and subfertility in relation to niche development and increases QOL and improves sexual functioning.

Study objective

Primary objective: to study the (cost) effectiveness of double layer closure of the uterine scar after a caesarean delivery, in comparison to single layer closure, in the prevention of niche development and related menstrual spotting. Secondary objectives: to assess the effect of the intervention on quality of life, societal participation, sexual function and on niche development and on subfertility and societal costs.

Study design

Multicentre randomised controlled trial (superiority). Patients and ultrasound examiners will be blinded for allocation. Cost effectiveness analysis form a societal perspective alongside the trial.

Intervention

Double layer closure (unlocked) continuous running suture of the uterus using multifilament material (instructed by e-learning) compared with usual (single layer) closure of the uterus, using a continuous running multifilament suture.

Study burden and risks

Double layer closure requires only little efforts of care providers in comparison to usual provided care (mean time investment of 6 minutes to execute the double layer suturing instead of single layer suturing). There are no negative effects on short term outcomes and double layer closure may result in positive effect long term outcome but that is to be studied. The study requires only limited time investment from patients (3 digital questionnaires and one additional ultrasound).

Contacts

Public
Selecteer

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific

Selecteer

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients undergoing their first CS (planned or emergency)
• >=18 years old
• Sufficient command of the Dutch language

Exclusion criteria

• Patients with an indication for an emergency CS (suspicion of fetal distress)
• Inadequate possibility for counseling (e.g. patients in heavy pain without accurate therapy, insufficient language comprehension) who were not asked to sign informed consent earlier in the pregnancy
• Previous uterine major surgery (e.g. laparoscopic or laparotomic fibroid resection, septum resection)
• Patients with known causes of menstrual disorders (known cervical dysplasia, communicating hydrosalpinx, uterine anomaly or endocrine disorders disturbing ovulation)
• Placenta percreta during the current pregnancy
• >= 3 fetus during the current pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2016
Enrollment:	2290
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-06-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL55551.029.15