Niche development in the first year after a caesarean section and the influence of preterm birth and preeclampsia

Published: 05-03-2019
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Primary Objective: * To evaluate the presence and time of occurrence of a niche in women who underwent a caesarean delivery Secondary Objective(s): * To evaluate changes of niche size and thickness of the residual myometrium over time* To determine...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48920

Source
ToetsingOnline

Brief title
SCAR-VIEW study

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
Caesarean scar defect, isthmocele

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Caesarean scar defect, Niche development, Ultrasound

Outcome measures

Primary outcome

Niche presence in the weeks/months after the CS.

Secondary outcome

- Niche characteristics over time (including length, depth, width, RMT, AMT,

distance between niche and VV fold, distance between niche and internal os)

- Determination of the best moment after CS to evaluate a niche and perform

measurements by using ultrasonography

- Evaluation of the influence of preeclampsia and preterm birth during the CS

on niche development and possible changes over time

Study description

Background summary

Evaluation of the uterine scar after caesarean section (CS) by using ultrasound can detect niches (defects of the scar). The exact moment when a niche can be visualized and when it is the best moment to evaluate a niche is unknown. The origin of niches is hypothesized in literature. Preeclampsia and preterm birth during the CS possibly influence niche development.

Study objective

Primary Objective:
* To evaluate the presence and time of occurrence of a niche in women who underwent a caesarean delivery

Secondary Objective(s):
* To evaluate changes of niche size and thickness of the residual myometrium

over time
* To determine the best moment after CS to evaluate the CS scar and to perform niche measurements
* To evaluate the influence of preeclampsia and preterm birth during the CS on the moment of niche development and its changes over time

Study design

Prospective cohort study

Study burden and risks

Participants will receive 5-6 transvaginal ultrasounds. The first ultrasound will be performed during hospitalisation after CS; the second will be combined with the regulair outpatient control after CS. For the other 3-4 ultrasounds participants will come extra to the hospital. There are no risks linked to transvaginal ultrasound.

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

- Patients who underwent their first CS (primary or secondary) in VUmc
- Sufficient command of the Dutch or English language
- * 18 years old
- Participants of the 2Close study, who agreed to undergo multiple ultrasounds in the first year after CS (Amendment 7 of the 2Close study *The cost effectiveness of double layer closure of the caesarean (uterine) scar in the prevention of gynaecological symptoms in relation to niche development*, registered at CCMO in ToetsingOnline (number NL55551.029.15) and at the METc VUmc (protocol number 2015.462), describes the same study method as current study. Data will be used in the SCAR-VIEW study. Sample size (n<=85) will not change.)

Exclusion criteria

- Insufficient language comprehension
- Age < 18 years

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2019

Enrollment:	85
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2020
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: 22134
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66399.029.18
OMON	NL-OMON22134