SCAR-VIEW study

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Many studies described a niche (defect of the uterine scar) to be visible after a prior caesarean section (CS) by using ultrasonography. The exact moment when a niche can be visualized and the best moment to evaluate it is unknown; most studies...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22134

Bron
NTR

Verkorte titel
SCAR-VIEW study

Aandoening

Niche, Caesarean scar defect, Caesarean section, Ultrasound, Preeclampsia, Preterm birth. Niche, Defect sectiolitteken, Sectio Caesarea, Keizersnede, Echo, Pre-eclampsie, Vroeggeboorte.

Ondersteuning

Primaire sponsor: VU medical hospital
Overige ondersteuning: VUmc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Niche prevalence in the weeks/months after CS

Toelichting onderzoek

Achtergrond van het onderzoek

Many studies described niches (scar defect) to be visible after a prior caesarean section (CS) by using ultrasonography. The exact moment when a niche can be visualized and the best moment to evaluate it is unknown; most studies evaluate the CS scar between 3 to 12 months after CS.
Also, the precise pathophysiology underlying genesis of CS scar defects is unknown, but it is likely to be related to abnormal healing of the myometrium. Some studies show that preeclampsia and preterm caesarean delivery are possibly related to disturbed healing and thereby development of a niche.

Objective of the study:

The aim of the study is to evaluate the time of occurrence of a niche in women who underwent a caesarean delivery; to evaluate changes of niche measurements over time and to determine the best moment in time after CS to evaluate the CS scar. Also, the influence of preeclampsia and preterm birth during the CS on the moment of niche development and its changes over time will be evaluated.

Doel van het onderzoek

Many studies described a niche (defect of the uterine scar) to be visible after a prior caesarean section (CS) by using ultrasonography. The exact moment when a niche can be visualized and the best moment to evaluate it is unknown; most studies evaluate the CS scar between 3 to 12 months. Also, the precise pathophysiology underlying genesis of CS defects is uncertain.
Preeclampsia and preterm birth are hypothesized to be associated with abnormal healing of the myometrium assuming that to cause niche development.

Onderzoeksopzet

3-4 days after CS (during hospitalization), 6 weeks (combined with visit outpatient clinic), 9 weeks, 12 weeks, 6 months, 12 months after CS.

Onderzoeksproduct en/of interventie

Participants will receive 6 transvaginal ultrasounds in the first year after CS, at 3-4 days (baseling), 6, 9 and 12 weeks, 6 and 12 months.
After analysis of the results of the first 10 participants, it will be decided whether to drop 1 or 2 time moments. In case no niche is observed during normal transvaginal ultrasound or the

technique is inconclusive, a Saline Infusion Sonohysterography (SIS) or Gel Installation Sonography (GIS) will be performed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All women (>18 years old) who received a caesarean section in VU medical hospital.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Age under 18 years, insufficient comment of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	85
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48920
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6743
NTR-old	NTR6921
CCMO	NL66399.029.18
OMON	NL-OMON48920

Resultaten