Scar Evaluation after Caesarean by Ultrasound Registry

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The primary hypothesis is that an association exists between the presence of a niche and abnormal uterine bleeding in women who had a previous caesarean section.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20066

Bron
NTR

Verkorte titel
SECURE

Aandoening

Nederlands: Niche, Sectio caesarea, Uterusruptuur, Abnormaal vaginaal bloedverlies, Metrorragie, Intermenstrueel bloedverlies

Engels: Niche, caesarean section, Uterine rupture, Abnormal uterine bleeding

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. A well circumscribed anatomical niche classification
2. A difference in uterine bleeding pattern between women with different niche types (based on the classification)

Toelichting onderzoek

Achtergrond van het onderzoek

While the caesarean section (CS) rate is increasing in most Western countries, the long-term effects of this procedure are poorly studied. In this observational prospective cohort study we will evaluate abnormal uterine bleeding and uterine rupture after CS.
Ultrasonography shows a ‘niche’ at the site of the uterine caesarean scar in the majority of women with a CS in the past history. A niche is a triangular, anechoic area at the presumed site of incision. Our primary objective is to develop an anatomical classification of niches and evaluate if this classification can be related to the degree of abnormal uterine bleeding. Our secondary objective is to demonstrate that the presence of a niche and thickness of the lower uterus segment (LUS) during subsequent pregnancy, can predict dehiscence or rupture of the uterus in women with previous caesarean delivery.
The study population consists of women who have had a caesarean delivery 6 to 12 months ago. Gel instillation sonohysterography (GIS) is performed to detect a niche and women are asked to fill in a questionnaire and keep a diary card to discover abnormal uterine bleeding. The questionnaire will be repeated every year for the duration of 5 years.
In case of subsequent pregnancy, transvaginal ultrasound will be performed between 16 and 20 weeks’ and between 36 and 38 weeks’ gestation to detect the presence of a niche and measure the thinnest zone of the LUS. The course of the pregnancy and delivery are recorded. Special attention is paid to any sign of uterine dehiscence or rupture.

Doel van het onderzoek

The primary hypothesis is that an association exists between the presence of a niche and abnormal uterine bleeding in women who had a previous caesarean section.

Onderzoeksproduct en/of interventie

Gel instillation sonohysterography is performed 6 to 12 months after caesarean section to detect a niche. Women are asked to fill in a questionnaire and keep a diary card to discover abnormal uterine bleeding.
In case of subsequent pregnancy, transvaginal ultrasound is performed to detect the presence of a niche and measure the thinnest zone of the lower uterus segment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Caesarean delivery in the past history
2. Signed informed consent form

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy
2. Pelvic inflammatory disease

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2007
Aantal proefpersonen:	224
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL956
NTR-old	NTR982
Ander register	:

Register	ID
ISRCTN	ISRCTN39988897

Resultaten