A Pilot-study to determine the (cost)effectiveness of the adhesion barrier 4DryField® PH in prevention of dysmenorrhea, pain and niche-related problems after Caesarean sections

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4DryField® PH on the uterine wound reduces adhesions between the uterus and bladder/abdominal wall and as a consequence reduction of dysmenorrhea, pelvic pain and niche related problems after caesarean sections.

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

Samenvatting

ID

NL-OMON23062

Bron
Nationaal Trial Register

Verkorte titel
4DryField Study

Aandoening

Caesarean sectio, scar defect, niche, abnormal uterine bleeding, dysmenorrhea
Sectio caesarean, litteken defect, niche, abnormaal uterien bloedverlies, dysmenorroe

Ondersteuning

Primaire sponsor: Amsterdam UMC, VUmc
Overige ondersteuning: PlantTec Medical GmbH

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- dysmenorrhea 9 months* after the CS

Toelichting onderzoek

Achtergrond van het onderzoek

The increasing CS rate has stimulated an interest in the potential long term morbidity of CS scar, such as uterine rupture or malplacentation. Other less severe, but more prevalent long term symptoms are gynecological symptoms and subfertility. There is a strong association between a niche and these complains. A niche (sometimes called a caesarean scar defect) is defined as a defect in the myometrium of at least 2mm at the site of the uterine CS scar and was observed in 50 to 60% of the patients after a CS. Apart from niche formation, development of adhesions is another complication of a CS, which possibly contributes to female subfertility, pelvic pain, complications in surgeries and spotting. The hypothesis is that adhesions may induce niche development due to retraction of the scar tissue, which pulls on the uterine scar towards the abdominal wall. To prevent these retractile forces, the barrier agent 4DryField® can to be used. 4DryField® is a powder which is transformed into a viscous gel. The gel functions as a temporary mechanical barrier separating surgically traumatized tissue and ensuring the healing of the respective surfaces. It is already used in daily practice and was shown to be efficient in prevention of adhesion formation in gynecological surgery as well as general surgery and animal models although no publication is available describing its effects after a CS.

Doel van het onderzoek

4DryField® PH on the uterine wound reduces adhesions between the uterus and bladder/abdominal wall and as a consequence reduction of dysmenorrhea, pelvic pain and niche related problems after caesarean sections.

Onderzoeksopzet

Dysmenorrhea at 3 and 9 months after the CS, measured on a NRS from 0 to 10 is the main parameter, on which the sample size is also calculated. The study endpoint will be the 3-year follow-up evaluating fertility, niche related symptoms and medical consultation.

Onderzoeksproduct en/of interventie

Subjects will receive treatment with the investigational product 4DryField® PH after closure of the uterus. The powder is applied directly onto the uterine scar and then transformed into a gel through dripping with isotonic 0.9% sodium chloride solution.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients undergoing their first CS (planned or unplanned)
- Age ≥ 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with an indication for an emergency CS (suspicion of fetal distress), or patients in heavy pain without accurate therapy, and who were not informed about this study during pregnancy
- Previous uterine major surgery (e.g. laparoscopic or fibroid resection by laparotomy, septum resection)
- Patients with known causes of menstrual disorders (known cervical dysplasia, communicating hydrosalpinx, uterine anomaly or endocrine disorders disturbing ovulation) or use of medication that can influence the frequency of blood loss (e.g. Ascal).

- Placenta percreta during the current pregnancy
- Patients with chronic abdominal pain
- Patients who do not speak Dutch or English

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
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:	01-11-2019
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL8078
Ander register	Amsterdam UMC : 2019-3942

Resultaten