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

Published: 18-11-2020
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Primary objective: to study the (cost) effectiveness of applying the 4DryField barrier on the uterine scar after a caesarean delivery, in the prevention of adhesions, niche development and related gynecological symptoms. Secondary objectives: to...

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

Summary

ID

NL-OMON49995

Source
ToetsingOnline

Brief title
4DryField Study

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
Adhesions, dysmenorrhea

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Plantec Medical GmbH;Luneburg;Duitsland

Intervention

Keyword: Adhesion barrier, adhesions, caesarean section, dysmenorrhea

Outcome measures

Primary outcome

Dysmenorrhea 9 months after the CS

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

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.

Study objective

Primary objective: to study the (cost) effectiveness of applying the 4DryField barrier on the uterine scar after a caesarean delivery, in the prevention of adhesions, niche development and related gynecological symptoms.
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

Randomized controlled trial

Intervention

Aplication of adhesion prevention barriers (4DryField® PH) in intervention group during a caesarean section.

Study burden and risks

Applying the adhesion barrier requires only little efforts of care providers in comparison to usual provided care. There are no negative effects on short term outcomes and 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

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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)
- Sufficient command of the Dutch or English language
- >= 18 years old

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-12-2020
Enrollment:	114
Type:	Actual

Medical products/devices used

Generic name:	4DryField® PH is CE-certified medical device for hemostasis as well as adhesion prevention produced
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-11-2020
Application type:	First submission
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	NL72538.029.20
Other	Trial NL8078