The cost effectiveness of surgical closure of the uterine scar during a caesarean section (CS) in 2 layers (compared with 1 layer closure) to prevent gynaecological symptoms associated with a defect in CS scar.

Gepubliceerd: 29-10-2015 Laatst bijgewerkt: 18-08-2022

Double layer closure of the uterine scar using unlocked continuous running sutures reduces menstrual disorders and pain and subfertility in relation to niche development and increases QOL and improves sexual functioning.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28023

Bron
NTR

Verkorte titel
2Close study

Aandoening

Double layer closure, Caesarean sectio defect, niche, abnormal uterine bleeding

2 lagen sluiten, Sectio caesarea litteken defect, niche, abnormaal uterien bloedverlies

Ondersteuning

Primaire sponsor: VU medical centre
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome: post- and intermenstrual spotting 9 months after randomization.

Toelichting onderzoek

Achtergrond van het onderzoek

Double layer compared to single layer closure of the uterus after a caesarean section (CS) leads to a thicker myometrial layer at the site of the CS scar (residual myometrium) and possibly decreases the development of niches. A niche is a CS defect at the site of the uterine scar and is associated with gynaecological symptoms including postmenstrual spotting (OR 3.1 (1.5 – 6.3)). It is also associated with failure of trail of labour after CS and possibly with subfertility. In the Netherlands single layer closure of the uterus is performed by 92% of the gynaecologists. In this study we will compare double layer closure with single layer closure of the (uterine) SC scar to study the effect on postmenstrual spotting 9 months after CS (primary outcome).

This is a multicenter trial which will be performed in the Netherlands.

Doel van het onderzoek

Double layer closure of the uterine scar using unlocked continuous running sutures reduces menstrual disorders and pain and subfertility in relation to niche development and increases QOL and improves sexual functioning.

Onderzoeksopzet

Primary study parameter:
Number of days of postmenstrual spotting 9 months after the CS, defined as intermenstrual (bleeding after at least 1 day without bleeding) or postmenstrual spotting (little amounts of red or brown blood loss immediately following normal menstruation) after 9 months.

Secondary study parameters:

- Intermediate (>2 days) or severe (>4 days) spotting and menstruation characteristics (menstrual score chart)

- Menstrual pain (VAS)

- QOL (SF36, EQ-5D-5L)

- Sexual function (FSFI)

- Societal reintegration (PROMIS; SF8a)

- Return to normal activities

- Existence of a niche (>2mm TV-US), large niches (>50% AND uterine wall< 3mm) and niche characteristics on TV-US including residual myometrium

- Peri-operative complications and surgery time

- Costs measured with a specifically adapted questionnaire (iMCQ) from a societal perspective

- Applied medical and surgical therapies because of niche related gynaecological symptoms within 9 months and 3 year follow-up

Of patients willing to conceive:

- Percentage of patients that conceived within 3 years follow-up.

- Percentage of patients with ongoing pregnancy within 3 years follow-up

- Time to conceive

- Applied therapies/interventions to improve fertility

Onderzoeksproduct en/of interventie

Double layer closure (unlocked) continuous running suture of the uterus using multifilament material (instructed by e-learning) compared with usual (single layer) closure of the uterus, using a continuous running multifilament suture.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women (18 years or older) undergoing their first caesarean section.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria include patients with previous uterine surgery, patients with known other factors causing menstrual disorders and patients with placenta percreta.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-05-2016
Aantal proefpersonen:	2290
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-10-2015
Soort:	Eerste indiening

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	NL5380
NTR-old	NTR5480
CCMO	NL80-84300-98-62021 ZonMW,

Resultaten