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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28023

Source
NTR

Brief title
2Close study

Health condition

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

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

Sponsors and support

Primary sponsor: VU medical centre
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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

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

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2016
Enrollment:	2290
Type:	Actual

Ethics review

Positive opinion

Date:	29-10-2015
Application type:	First submission

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

Study results