Study to look after defects of the cesarean section scar with ultrasound and study for risk factors to develop a defect.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20224

Source
NTR

Brief title
SCAR

Health condition

cesarean section scar defects, niches, keizersnede littekendefect

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis Nieuwegein
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

1. Incidence scar defect > 2 mm by sonohysterography;

2. Risk factors for developing a scar defect.

Secondary outcome

1. Relation with bleeding disorders (menstruation longer than 10 days, post menstrual spotting, intermenstrual bleeding);

2. Differences in ultrasound (depht of defect) within one patient in longitudinal follow-up of primipara;

3. Relation with urinary incontinence measured by questionary.

Study description

Background summary

A prospective cohort study to investigate the incidence and risk factors for developing a cesarean scar defect. This is done by (sono)hysterography 6-12 weeks post partum and a questionair 6 weeks, 6 ,12 and 24 months post partum. Secondary outcome is to study the relation with bleeding disorders (prolonged menstruation and postmenstrual spotting). We also look longitudinal within a patient to study the appareances of the scardefect in time.

Study objective

Scar defect may give complications on long term. Study is to investigate if the defect is detectable with ultrasound.

Study design

1. (Sono)hysterography 6-12 weeks post partum;

2. Questionairy 6 weeks, 6, 12 and 24 months post partum;

3. (Sono)hysterography 6-12 months post partum (primipara).

Intervention

1. 6-12 weeks postpartum transvaginal ultrasound and sonohysterography;

2. Questionairy 6 weeks, 6, 12 and 24 months post partum.

Contacts

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Eligibility criteria

Inclusion criteria

1. Have had a cesarean section less than 12 weeks ago;

2. Good understanding and use of Dutch language.

Exclusion criteria

1. < 18 year;

2. Mutliple pregnancy;

3. Known uterusanomaly;

4. Pregnancy at time of ultrasound;

5. Pelvic inflammatoiry disease.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2008
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	05-05-2011
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	NL2749

Register	ID
NTR-old	NTR2887
Other	VCMO : R-07.14a
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A