SCAR study
Sonohysterographic evaluation of caesarean scar defects and determination of risk factors

Published: 27-09-2007
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Determination of the incidence of a scar defect .Determination of riskfactors for develpment of scar defects

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational invasive

Summary

ID

NL-OMON31061

Source
ToetsingOnline

Brief title
SCAR

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Obstetric and gynaecological therapeutic procedures

Synonym
niche, scar defect

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bleedingdisorders, cesarean section, Gel- infusion- sonohysterography, scar-defects

Outcome measures

Primary outcome

incidenty scar defects

risk factors for scar defects

Secondary outcome

relation bleedingproblems and scar defects

relation scar defects and complications subsequent pregnancy

Study description

Background summary

The cesarean section rate rises in the Netherlands. There is little known about the long term effects of this operation. It is known that a cesarean section in the past gives more complications a subsequent pregnancy. By use of sonohysterography and hysteroscopy there is a echolucent triangular space visible at the presumed site of the cesarean scar. The clinical relevance of this scar defect or niche is still unclear.

Study objective

Determination of the incidence of a scar defect .
Determination of riskfactors for develpment of scar defects

Study design

Observational prospective cohort study.

Study burden and risks

patient undergo a Gel-infusion sonohysterography during their regular visit

post partum. They also fulfill 3 questionnaire in a year time.
There are no complications related to a Gel infusion sonohysterography known in the literature. Theoreticaly there is a possibility of developing a endometritis.

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

cesarean section
18 years and older
delivery in Sint Antonius Ziekenhuis Nieuwegein

Exclusion criteria

New pregnancy during investigation
pelvic inflammatoir disease
twins

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	27-09-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	20-07-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL18722.100.07