

# 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 development of scar defects

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Pregnancy, labour, delivery and postpartum conditions
<b>Study type</b>	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:** bleeding disorders, cesarean section, Gel- infusion- sonohysterography, scar-defects

## Outcome measures

### Primary outcome

incident scar defects

risk factors for scar defects

### Secondary outcome

relation bleeding problems 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 risk factors for development 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. Theoretically there is a possibility of developing a endometritis.

## Contacts

### **Public**

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Nederland

### **Scientific**

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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