# Scar Evaluation after Caesarean by Ultrasound Registry

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Ethical review	Approved WMO
Status	Pending
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Observational invasive

# Summary

### ID

NL-OMON31818

**Source** ToetsingOnline

Brief title SECURE

# Condition

• Menstrual cycle and uterine bleeding disorders

#### Synonym

1)Niche 2)Triangular notch at the site of the uterine caesarean scar

# Research involving

Human

### **Sponsors and support**

**Primary sponsor:** Vrije Universiteit Medisch Centrum **Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

Keyword: Abnormal uterine bleeding, Caesarean section, Niche, Uterine rupture

### **Outcome measures**

#### **Primary outcome**

1) A well circumscribed anatomical niche classification

2) A difference in uterine bleeding pattern between women with different niche

types (based on the classification)

#### Secondary outcome

1) To demonstrate a relation between niche and LUS thickness

2) To demonstrate an association between the presence of a niche and

(in)complete uterine rupture

3) To demonstrate an association between LUS thickness and (in)complete uterine rupture

4) To test the hypothesis that the presence of a niche negatively affects fertility, i.e. that the duration to get an ongoing pregnancy is increased in women with a niche compared to women without a niche. If a niche affects fertility, the hypothesis will be tested that a niche influences the endometrial secretion protein pattern.

# **Study description**

#### **Background summary**

While the caesarean section (CS) rate is increasing in most Western countries, the long-term effects of this procedure are poorly studied. In this study we will evaluate abnormal uterine bleeding, subfertility and uterine rupture after CS.

#### **Study objective**

Ultrasonography shows a niche at the site of the uterine caesarean scar in the majority of women with a CS in the past history. A niche is a triangular, anechoic area at the presumed site of incision. Our primary objective is to develop an anatomical classification of niches and evaluate if this classification can be related to the degree of abnormal uterine bleeding. Our secondary objective is to demonstrate that the presence of a niche and thickness of the lower uterus segment (LUS) during subsequent pregnancy, can predict dehiscence or rupture of the uterus in women with previous caesarean delivery.

As an addition, we want to evaluate if there is a relation between the presence of a niche and subfertility. If this relation can be demonstrated, the hypothesis will be tested that a niche negatively affects the endometrial secretion pattern.

### Study design

In an observational prospective cohort study, gel instillation sonohysterography (GIS) is performed 6 to 12 months after CS to detect a niche. The depth and shape, the thickness of the residual myometrium and the thickness of the myometrium bordering the scar will be recorded in order to develop a classification. Endometrial secretion will be obtained by performing endometrial aspiration just before the GIS. Two blood samples will be taken for anti-Müllerian hormone (AMH) serum level measurement and one spare sample for stored serum. Women are asked to fill in a questionnaire and keep a diary card to discover abnormal uterine bleeding. The questionnaire will be repeated every year for the duration of 5 years and GIS will only be repeated if there is an indication for sonohysterography. In case of secondary subfertility women will be contacted by the investigator and receive additional questions.

In 6 women with niche and 6 women without niche, GIS will be repeated two more times. Ultrasound images of the niche will be obtained in the follicular phase, the phase around the ovulation and the luteal phase.

In case of subsequent pregnancy, transvaginal ultrasound will be performed between 16 and 20 weeks\* and between 36 and 38 weeks\* gestation to detect the presence of a niche and measure the thinnest zone of the LUS. The course of the pregnancy and delivery are recorded. Special attention is paid to any sign of uterine dehiscence or rupture.

Women with a history of caesarean section, without any fertility problems in the past, and now visiting the outpatient clinic because of secondary subfertility will undergo the same examinations: GIS, endometrial aspiration and blood withdrawal. They will also be asked to fill in a questionnaire and to keep a diary card to discover abnormal uterine bleeding.

#### Study burden and risks

The burden, associated with participation, includes a visit of the VU University Medical Center to undergo GIS or transvaginal ultrasonography and blood withdrawal. Endometrial aspiration will be performed during the GIS which gives no additional inconvenience. The risk associated with GIS and transvaginal ultrasound is very low. Furthermore, participants will be requested to fill in a questionnaire on a yearly base, during a period of 5 years. In case of secondary subfertility women will receive additional questions.

GIS will be repeated two more times in 12 volunteers.

The benefit of the SECURE-study is that women with complaints of abnormal uterine bleeding might be diagnosed with having a niche. In case of a niche and the presence of associated symptoms, further examination and treatment can follow.

# Contacts

#### Public

Vrije Universiteit Medisch Centrum

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Caesarean delivery in the past history Signed informed consent form

### **Exclusion criteria**

Pregnancy Pelvic inflammatory disease (PID)

# Study design

# Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	224

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Type:

Anticipated

### Medical products/devices used

Generic name:	transvaginal ultrasound and gel instillation
	Soliollysterography (GIS)
Registration:	Yes - CE intended use

# **Ethics review**

Approved WMO
Application type:
Review commission:

First submission METC Amsterdam UMC

# **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
ССМО	NL17750.029.07
Other	NTR982 / ISRCTN39988897