

# Scar Evaluation after Caesarean by Ultrasound Registry

<b>Submission date</b> 27/06/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/08/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Scar Evaluation after Caesarean by Ultrasound Registry

**Acronym**

SECURE

**Study objectives**

The primary hypothesis is that an association exists between the presence of a niche and abnormal uterine bleeding in women who had a previous caesarean section.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the medical ethics committee of Vrije University Medical Centre (METc VUmc) on the 4th September 2007 (ref: 2007/126).

**Study design**

Observational prospective cohort study

**Primary study design**

Observational

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Abnormal uterine bleeding, uterine rupture, caesarean section

**Interventions**

Gel instillation sonohysterography is performed 6 to 12 months after caesarean section to detect a niche. Women are asked to fill in a questionnaire and keep a diary card to discover abnormal uterine bleeding.

In case of subsequent pregnancy, transvaginal ultrasound is performed to detect the presence of a niche and measure the thinnest zone of the lower uterus segment.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. A well circumscribed anatomical niche classification. The niches will be measured by ultrasound 6 - 12 months after caesarean section
2. A difference in uterine bleeding pattern between women with different niche types (based on the classification), with a follow-up of the bleeding pattern for 5 years after caesarean section

**Key secondary outcome(s)**

1. To demonstrate a relation between niche and Lower Uterine Segment (LUS) thickness in case of a subsequent pregnancy. The LUS will be measured between 16 and 20 weeks gestation, and between 36 and 38 weeks gestation
2. To demonstrate an association between:

2.1. Niche and (in)complete uterine rupture

2.2. LUS thickness and (in)complete uterine rupture

To identify an (in)complete rupture, the course of the pregnancy will be recorded

**Completion date**

01/07/2012

## **Eligibility**

**Key inclusion criteria**

1. Caesarean delivery in the past history
2. Signed informed consent form

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Female

**Total final enrolment**

225

**Key exclusion criteria**

1. Pregnancy
2. Pelvic inflammatory disease

**Date of first enrolment**

01/07/2007

**Date of final enrolment**

01/07/2012

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Vrije University Medical Centre (VUMC)

Amsterdam

Netherlands

1081 HV

# Sponsor information

## Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

## ROR

<https://ror.org/00q6h8f30>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/01/2011	05/08/2021	Yes	No