

Scar Evaluation after Caesarean by Ultrasound Registry

Submission date 27/06/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 27/06/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/08/2021	Condition category 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

Contact name
Dr A.J.M. Bij de Vaate

Contact details
Vrije University Medical Centre (VUMC)
Department of Obstetrics and Gynaecology
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+31 (0)20 444 3613
m.bijdevaate@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/07/2007

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

Age group

Not Specified

Sex

Female

Target number of participants

224

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)

Sponsor details

Department of Obstetrics and Gynaecology

Division of Reproductive Medicine

P.O. Box 7057

Amsterdam

Netherlands

1007 MB

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/english/>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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?
Results article		01/01/2011	05/08/2021	Yes	No