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Scar Evaluation after Caesarean by Ultrasound Registry

Submission date	Recruitment status	[X] Prospectively registered
27/06/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2021	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 rupture
To 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