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Evaluation of the caesarean section scar during pregnancies after uterine scar repair in comparison to controls without scar repair

Submission date
22/06/2021

Recruitment status
No longer recruiting

Registration date
28/07/2021

Overall study status
Completed

Last Edited
25/08/2022

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A niche is a defect at the site of the caesarean section scar in the uterine wall, and is associated with gynaecological, obstetric and fertility problems. Laparoscopic niche repair has been reported to reduce gynaecological symptoms and increase the thickness of the uterine wall at the side of the caesarean section scar (the residual myometrium thickness [RMT]) at 6 months after surgery. The RMT seems to have an important role in determining the risk of rupture /dehiscence of the uterine caesarean section scar in a later pregnancy. Although no exact cut-off point has been determined yet, a RMT of less than 3 mm before and during subsequent pregnancy was associated with uterine rupture or dehiscence after vaginal birth after caesarean section. The influence of laparoscopic niche repair before pregnancy on the RMT in pregnancy and its associated risk of uterine rupture or dehiscence is unknown. The aim of this study is to evaluate the effect of laparoscopic niche repair on the RMT and niche size before and after surgery and in a later pregnancy compared to patients without previous niche surgery.

Who can participate?
Pregnant women aged 18 years and over who participated in the Dutch Lapniche study or Niche Cohort study

What does the study involve?
A transvaginal ultrasound scan will be performed in the first, second and third trimester of pregnancy for RMT and niche measurements. Obstetric outcomes are obtained from participants' medical files from the time of delivery.

What are the possible benefits and risks of participating?
Participants do not benefit from participating in this study. Participation can contribute to more knowledge about RMT and niche changes during pregnancy. A disadvantage of participating in the study can be the extra time that it will take.

Where is the study run from?
VU University Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?
February 2010 to December 2019

Who is funding the study?
Vrije Universiteit Amsterdam (Netherlands)

Who is the main contact?
Prof. Dr J.A.F. Huirne
j.huirne@amsterdamumc.nl

Contact information

Type(s)
Scientific

Contact name
Prof J.A.F. Huirne

Contact details
Department of Obstetrics and Gynaecology
Amsterdam UMC, location VUmc
Postbus 7057
Amsterdam
Netherlands
1007MB
+31 (0)20 4441486
j.huirne@amsterdamumc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ABR: NL37922.029.11

Study information

Scientific Title
Changes of the uterine niche during pregnancies after laparoscopic niche resection in comparison to controls without niche surgery

Study objectives
It is hypothesized that the residual myometrium thickness (RMT) in women with previous laparoscopic niche resection is larger and niche size is smaller during pregnancy than in women with a niche, without niche repair prior to the pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/10/2011, Ethical Board VU University Medical Center (Amsterdam UMC, location VUmc, BS7 room H-565, Postbus 7057, 1007 MB Amsterdam, Netherlands; +44 (0)20 4445585; metc@vumc.nl), ref: 2011/297

Study design
Observational prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subsequent pregnancy after previous niche resection

Interventions
An observational study of women with a niche after previous caesarean section, diagnosed before pregnancy, and followed up during subsequent pregnancy. There are two arms: women with a previous laparoscopic niche resection (intervention) and women without niche resection (expectant group).

The participants receive a TVUS before pregnancy and at 12, 20 and 30 weeks' of gestational age (GA).

Intervention Type
Procedure/Surgery

Primary outcome(s)
RMT obtained from the data of the Lapniche study and Niche cohort study before pregnancy and measured using transvaginal ultrasound (TVUS) in the first, second and third trimester of pregnancy

Key secondary outcome(s))
1. Niche presence and niche measurements obtained from the data of the Lapniche study and Niche cohort study before pregnancy and determined using TVUS in the first, second and third trimester of pregnancy
2. Obstetric outcomes (gestational age (GA) at time of delivery, obtained from medical files from time of delivery
3. Mode of delivery, obtained from medical files from time of delivery
4. Uterine dehiscence and rupture, obtained from medical files from time of delivery
5. Blood loss, obtained from medical files from time of delivery
6. Birth weight, obtained from medical files from time of delivery
7. Apgar score, obtained from medical files from time of delivery
8. Admission to neonatal care unit, obtained from medical files from time of delivery

Completion date

31/12/2019

Eligibility

Key inclusion criteria
Lapniche group: participants of the LapNiche trial (CCMO - NL37922.029.11)
Expectant group: participants of the Niche Cohort study (https://www.trialregister.nl/, trial number NL6844)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
101

Key exclusion criteria
Age <18 years or not able to understand Dutch

Date of first enrolment
01/02/2012

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Amsterdam UMC, location VUmc
Department Obstetrics and Gynecology
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Center

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
University/education

Funder Name
Vrije Universiteit Amsterdam

Alternative Name(s)
VU University Amsterdam, VU University, VU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study are/will be available upon request from Prof. Dr J.A.F. Huirne (j.huirne@amsterdamumc.nl). Datasets include RMT and niche measurements and obstetric outcomes. These will become available after the publication of the results. The dataset is anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/07/2022	25/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			26/07/2021	No	No
Protocol file			26/07/2021	No	No