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The effect of the laparoscopic reconstruction of a caesarean scar (Niche)

Submission date
23/04/2013

Recruitment status
No longer recruiting

Registration date
27/02/2014

Overall study status
Completed

Last Edited
14/09/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
In Western countries, caesarean rates are rising. A niche is a cavity that can develop at the site of an old caesarean section scar which occurs in approximately 60% of the women who had a caesarean section. A niche can cause abnormal uterine blood loss, intracavitary accumulation of fluid and inaccessibility of the uterine cavity (i.e. for intra-uterine insemination or embryo transfer). Surgical therapy can possibly reduce these complaints. In general, a hysteroscopic resection (surgery using a thin telescope called a hysteroscope and no incision is made) and/or coagulation of the vessels in the niche will be sufficient. However, in the case of a large niche, a laparoscopic resection (surgery in which only small incisions are made) and closure of the niche are preferred. It is assumed that in these cases the risk of bladder injury during hysteroscopic niche resection is too high. The main aim is to study the effectiveness of laparoscopic niche resection in the treatment of niche-related bleeding disorders. Other aims are to study the effect of laparoscopic niche resection on menstrual pain, quality of life and fertility, intracavitary accumulation of fluid and niche characteristics.

Who can participate?
Women with niche-related abnormal uterine blood loss, dysmenorrhoea (painful periods) or accumulation of intracavitary fluid with residual myometrium (middle layer of the uterine wall) < 3mm

What does the study involve?
All patients will undergo surgery (laparoscopic niche resection) and will be followed up for 6 months after the surgery.

What are the possible benefits and risks of participating?
We expect that laparoscopic reconstruction of a niche will reduce prolonged menstrual bleeding, and associated menstrual pain and as a consequence will improve related quality of life. In addition, we expect the laparoscopic niche reconstruction to reduce the accumulation of intra-uterine fluid. We additionally expect the reconstruction to increase the thickness of the remaining myometrium between the bladder and the niche. Risks of the intervention include bleeding and bladder injury during the surgery and incomplete niche reconstruction.

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?
The study started in September 2009 and will continue until December 2015.

Who is funding the study?
VU University Medical Center (Netherlands).

Who is the main contact?
Prof. Dr. H.A.M. Brolmann, h.brolmann@vumc.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ABR: NL37922.029.11

Study information

Scientific Title
The effect of the laparoscopic reconstruction of a caesarean scar (Niche): an observational pilot study

Acronym
LapNiche

Study objectives

Laparoscopic niche resection will reduce the complaints and possibly increase fertility chances in women with a niche with residual myometrium < 3 mm and complaints of abnormal uterine blood loss / dysmenorrhoea or intracavitary accumulation of fluid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Board VUmc, 02/10/2011, ref.:2011/297

Study design
Observational study of an intervention (prospective cohort study)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Abnormal Uterine Bleeding / Niche resection

Interventions
This is an observational study of an intervention, laparoscopic niche resection.

There is only one study arm. The laparoscopic niche resection/reconstruction is an operative laparoscopy where the roof of the niche is resected and the myometrial wound is closed in two layers with Vicryl. The operation is performed under hysteroscopic guidance and lasts about 2-3 hours. The patient is followed up for 6 months after the intervention. Symptoms of postmenstrual spotting are assessed and a transvaginal ultrasound is made and compared to baseline values.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure

Reduction of abnormal uterine blood loss in days, measured at baseline and after 3, 6, 9 and 12 months

Secondary outcome measures
1. Quality of life (SF36)
2. Dysmenorrhoe
3. Fertility/pregnancy
4. Intracavitary accumulation of fluid

All above outcomes measured at baseline and after 3, 6, 9 and 12 months

Overall study start date
01/01/2009

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. A niche with residual myometrium < 3 mm (as measured with SIS / GIS)
2. Complaints of abnormal uterine blood loss, dysmenorrhoea or accumulation of intracavitary fluid
3. Premenopausal women aged above 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

Total final enrolment
133

Key exclusion criteria
1. Pregnancy
2. Age below 18
3. Other disorders that may induce spotting [polyps (everywhere in the uterus/cervix are exclusion criteria except those in the niche)], fibroids, known atypical endometrial cells, cervical dysplasia, cervical or pelvic infection, assumed malignancy, irregular cycle (>35 days or intercycle

variation of 2 weeks or more)
4. Contra-indications for spinal or general anaesthesia

Date of first enrolment
01/01/2009

Date of final enrolment
12/12/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of Obstetrics and Gynaecology
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Center (Netherlands)

Sponsor details
C/O Prof. Dr. H.A.M. Brolmann
Department of Obstetrics and Gynaecology
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.com/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Time of the researchers is paid by the institution VU University Medical Center (VUmc) (Netherlands).

Funder Name
As it is an observational study of usual care the direct costs are reimbursed by the insurance company.

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	Long-term follow-up	12/09/2023	14/09/2023	Yes	No