Studie naar hysteroscopische behandeling van littekendefecten na sectio bij patienten met abnormaal uterien bloedverlies.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26833

Source
NTR

Brief title
HysPAS

Health condition

abnormal uterine bleeding
cesarean scar defect
hysteroscopic resection
abnormaal uterien bloedverlies
littekendefect na sectio
hysteroscopie

Sponsors and support

Primary sponsor: S. Veersema, gynaecoloog St Antonius Ziekenhuis, Nieuwegein
L.F. van der Voet, gynaecoloog Deventer Ziekenhuis, Deventer
Prof H.A.M. Brollman, gynaecoloog VU Medisch Centrum Amsterdam
Source(s) of monetary or material Support: stichting nieuwegyn

Intervention

Outcome measures

Primary outcome

Decrease in days of bloodloss/spotting
(pictorial chart).

Secondary outcome

1. Quality of life by SF -36 questionaire;

2. Complications;

3. Decrease in dysmenorrhoe by VAS score;

4. Satisfaction patients with therapy by questionaire.

Study description

Background summary

There is a association between uterine bleeding disorders and a cesarean scar defect. Patients with abnormal uterine bleeding and a cesarean scar defect in the uterus (seen by contrast sonohysterography) will undergo a hysteroscopic resection of the scarred tissue. Primairy outcome is decrease of days of abnormal bleeding. Secundairy outcome are patients satisfaction, quality of live and decrease of dysmenorrhoe. Also the safety of the procedure will be investigated. Patients fullfill a questionaire and a pictorial chart of their menstruation before operation and 3 and 12 months post operative. And will have a contrast sonohysterography before operation and 3 moths post operative.

Study objective

Is resection of cesarean scar tissue in patients with a cesarean scar defect and abnormal bleeding a safe and effective treatment.

Study design

Questionaire at inclusion, 3 en 12 months post operative.

Intervention

Hysteroscopic resection of cesarean scar tissue in uterus/cervix.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with a cesarean scar defect and abnormal uterine bleeding.

Exclusion criteria

1. Pregnancy;

2. Wish for pregnancy in future;

3. Other gynaecological problems (myoma, polyps).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	22
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 32934
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1812
NTR-old	NTR1922
CCMO	NL28897.100.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32934

Study results

Summary results
N/A