Pilotstudy on effect of hysteroscopic resection treatment of patients with abnormal uterine bleeding and a scardefect after a cesarean section

Published: 29-10-2009
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To study if a hysteroscopic resection a safe and effective treatment is for intermittend/post menstrual bloodloss or spotting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Menstrual cycle and uterine bleeding disorders
Study type	Interventional

Summary

ID

NL-OMON32934

Source
ToetsingOnline

Brief title
HysPAS

Condition

- Menstrual cycle and uterine bleeding disorders

Synonym
intermittend bleeding, spotting

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: stichting nieuwegyn

Intervention

Keyword: abnormal uterine bleeding, hysteroscopy, section scar, therapy

Outcome measures

Primary outcome

decrease in days of post menstrual bloodloss

Secondary outcome

decraese dysmenorrhia

Increase of Quality of live(measured by SF -36 questionnaire)

Study description

Background summary

The cesarean section rate is rising. Patients with a history of a cesarean section can have intermenstrual bloodloss and spotting after the menstruation due to a cesarean scar defect in the uterus. There is no evidence based therapy for this problem at the moment.

Study objective

To study if a hysteroscopic resection a safe and effective treatment is for intermittend/post menstrual bloodloss or spotting.

Study design

prospective cohort study

Intervention

Hysteroscopic resection of scarred tissue in the anterior wall of the cervical canal.

Study burden and risks

Patients undergo a hysteroscopic resection of scarred tissue in daycare. The risk for perforation is being reduced by use of a ultrasound at the same time.

3 times the patients fullfil a questionnaire about quality of live (SF-36) ,
about contraception and obstetric hystory and about menstruation. They keep a menstruatrion record 3 times for 2 months

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

abnormal menstrual bleeding, intermittend bleeding or prolonged menstruation
history of cesarean section
scardefect seen by SIS or GIS
18 years of older
Dutch speaking and reading

Exclusion criteria

pregnancy or wish to become pregnant in future
presence of contra-indication for anaesthesia or hysteroscopy
(uncontrolled)endocrinological disorder
other gynaecologic pathology
use of coagulantia

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2010
Enrollment:	22
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	29-10-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	14-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26833
Source: NTR
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT1922
CCMO	NL28897.100.09