# Hysteroscopic resection of uterine scar defects (niche) in patients with abnormal bleeding, a randomised controlled trial

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

## Summary

### ID

NL-OMON39029

**Source**
ToetsingOnline

**Brief title**
HysNiche study

### Condition

- Menstrual cycle and uterine bleeding disorders

**Synonym**
CS scar defect, Isthmocele

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Abnormal uterine bleeding, Caesarean section scar defect, Hysteroscopy, Niche, Nicheresection

## Outcome measures

### Primary outcome

Primary: number of days with postmenstrual spotting in the first 6 months after

randomization

### Secondary outcome

Secondary: menstrual pattern (score card) and related pain (VAS) and

disturbance (VAS), quality of life (SF36, EuroQol), patient satisfaction,

sexual function (FSFI), medical consultation and medication use, complications,

sick leave, and costs (diary) after 3, 6 and 12 months after randomization.

Characterisitics of the niche (3 months after randomization, size/volume of the

niche).

# Study description

### Background summary

In western countries, caesarean rates are rising. A caesarean section can cause a niche (defect at the site of the uterine scar); the incidence of niche related postmenstrual spotting in the Netherlands is expected to be 60 %. Promising results are reported after an innovative minimally invasive hysteroscopic resection of these niches. However its (cost) effectiveness in comparison to a control group has to be proven.

### Study objective

Our primary objective is to study the effectiveness of hysteroscopic resection for niche related uterine bleeding disorders. The procedure will be performed in small niches with a residual myometrium of more than 3mm.
Our secondary objective is to asses the quality of life, sexual function and a

cost-effective analysis will be made

### Study design

The study is a multicentre randomized controlled trial. After the patiente has received the information letter and signed the informed consent she will be included and randomised. Patients will be randomly allocated to hysteroscopic resection or expectant management. Randomization will be performed centrally with the use of a permuted block design, stratified for recruiting centre.
After randomization the patients who undergo the intervention will be assessed by an anesthesiologist.

### Intervention

The patients allocated for hysteroscopic niche resection will undergo the procedure under spinal or general anaesthesia in lithotomic position. An experienced gynaecologist will asses the niche and the intra-uterine cavity according to standardized criteria. Resection will be performed using a 9mm resectoscope on a standardize way. In case of bipolar currency, 0,9 % NaCL and in case of monopolar, Sorbitol fluid will be used to induce distension of the uterine cavity. The distal part of the niche in utero is resected and the niche surface will be superficially coagulated under abdominal ultrasound guidance to assure sufficient distance to the bladder wall during resection. Possible polyps in the niche will be resected.

### Study burden and risks

Patients will be informed about the procedure and will be told that there is no evidence about the effectiveness of the therapy. The procedure will be in a research setting. The complications with a hysteroscopy will be told, i.e. bleeding, infection, perforation of the uterus or bladder, or adhesions in the uterine cavity post-operatively. In rare cases a defect of the bladder can occur, caused by coagulation of the surface of the niche. Therefore the procedure is not performed if the residual myometrium is less than 3mm. In a previous pilotstudy of 20 patients no complications occurred.
Also in every patient one specimen of blood will be collected for analysis of AMH ( marker of ovarian reserve capacity) in the future.

## 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

Patients with post menstrual spotting (more than 2 days or menstruation of at least 10 days) and a large niche(at least 2mm) with a residual myometrium more than 3 mm.

## Exclusion criteria

Patients aged below 18 or pregnant.
Other causes of postmenstrual spotting ( abnormalities in the uterine cavity)
Contraindications for general or spinal anesthesia.

# Study design

## Design

Study type: Interventional

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| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 12-07-2012 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 04-04-2012 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 16-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 10-07-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

## In other registers

| Register | ID |
| --- | --- |
| CCMO | NL38397.029.11 |