# MUST: Morcellation and Uterine Snare Resection Trial

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Snare resection is non-inferior to hysteroscopic morcellation and snare resection is cost-effective.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22926

**Bron**
NTR

**Verkorte titel**
MUST

**Aandoening**

Duckbill polyp snare, hysteroscopic morcellator, endometrial polyp, outpatient polypectomy

### Ondersteuning

**Primaire sponsor:** Maxima Medisch Centrum Veldhoven
**Overige ondersteuning:** fund = initiator - sponsor

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Complete removal of the polyp

# Toelichting onderzoek

### Achtergrond van het onderzoek

Endometrial polyps occur in both pre- and postmenopausal women and are often asymptomatic. When symptoms occur they most commonly include abnormal uterine bleeding. The vast majority of polyps are benign with a prevalence of atypia and malignancy of 0.8% and 3.1% respectively.
The first choice treatment for endometrial polyps is hysteroscopic resection. The miniaturisation of hysteroscopes and ancillary instrumentation coupled with enhanced visualisation has enabled hysteroscopic surgery to be performed in an outpatient setting without the need for general anesthesia. The removal of endometrial polyps with the Duckbill snare as an office procedure has first been described in 2005. Whilst the technology is feasible and effective it requires skills and experience in outpatient hysteroscopic surgery, which many gynecologists lack and this is reflected in the limited adoption of polyp snare procedures. The limited adoption can additionally be explained by to lack of publications supporting their use for the removal of endometrial polyps. The Duckbill polyp snare has been investigated in two studies, which showed the snare is a safe and efficient method and is well tolerated by patients.
In 2005 a new technology has become available called the hysteroscopic morcellator. Two recently conducted randomized controlled trials showed an overall efficacy of 92-98%.

The Duckbill polyp snare has two important advantages over the hysteroscopic morcellator. The snare can be used down the operating channel of a variety of continuous flow hysteroscopes, which are already being used in day-to-day use in gynaecological practice in outpatient settings. In contrast, the hysteroscopic morcellator system requires acquisition of specific hysteroscopes. Another advantage are the costs of the device, which are about six times lower for the Duckbill polyp snare in comparison with the hysteroscopic morcellation with a purchase price of respectively 55 euro and 304,32 euro.

Studies in which the hysteroscopic morcellator is compared with the Duckbill polyp snare are lacking therfore it is uncertain which method is the first choice method to remove endometrial polyps in an outpatient setting.

In this study we hypothesize that snare resection is non-inferior to hysteroscopic morcellation (primary outcome).
This is a multicenter trial which will be performed in the Netherlands.

### Doel van het onderzoek

Snare resection is non-inferior to hysteroscopic morcellation and snare resection is cost-effective.

**Onderzoeksopzet**

The primary outcome, completeness of polyp removal, will be analysed by logistic regression. We will adjust for confounders if necessary. To show non-inferiority the upper bound of the 95% CI for the difference in completeness of polyp removal should not exceed the prespecified non-inferiority margin of 10%.

Standard statistical methods will be used to analyse secondary outcomes.

Subgroup analyses based on the size of the polyp will be made as size influences the completeness of removal.
Analyses for all parameters will be by intention to treat. We will also perform a per protocol analysis, considering the non-inferiority design of the study.

We expect the effect on the quality of life will be comparable between the two procedures as we expect the Duckbill polyp snare to be non-inferior in the resection of polyps as compared to the hysteroscopic morcellator.

**Onderzoeksproduct en/of interventie**

Transcervical resection of polyps with the Duckbill polyp snare

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All consenting women with benign looking endometrial polyps

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women with malign looking endometrial polyps.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-05-2016 |
| Aantal proefpersonen: | 220 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5462 |
| NTR-old | NTR5606 |
| Ander register | ZonMW : ProjectNetAanvraag55208 |

# Resultaten

**Samenvatting resultaten**

Beelen P, Geomini PMAJ, Veersema S, Bongers MY. Hysteroscopic resection of endometrial polyps using the Duckbill Polyp Snare in an outpatient setting.2015. Unpublished.