

Randomized controlled trial of treatment of endometrial polyps in case of postmenopausal bleeding.

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Resection of endometrial polyp(s) in women with postmenopausal bleeding and endometrial thickness of more than 4 mm will lead to less recurrent bleeding than in women in whom no resection is performed.

| | |
|-----------------------------|-----------------------|
| Ethische beoordeling | Positief advies |
| Status | Werving gestopt |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON20104

Bron

NTR

Verkorte titel

RaTTeP

Aandoening

Women with postmenopausal bleeding and endometrial polyp(s).

Ondersteuning

Primaire sponsor: Sponsor is St. Antonius ziekenhuis

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Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the recurrence of postmenopausal bleeding.

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

The incidence of postmenopausal bleeding varies from 1.7- 14.6 per 1000 women, depending on age. The chance to find an endometrial carcinoma in women with postmenopausal bleeding varies between 1% and 24%, and is also dependent on age.

The prevalence of endometrial polyps in women with postmenopausal bleeding and an endometrium thickness of 5 mm or more is estimated to be 41%.

The Dutch guideline for diagnostics in case of abnormal vaginal bleeding in postmenopausal women focuses on diagnosing malignant pathology of the endometrium.

The guideline uses endometrium thickness as a first screening tool to exclude cancer. Only in case the bleeding persists, a hysteroscopy is advised to diagnose benign treatable pathology. No data exists either about the recurrence of bleeding in women with postmenopausal bleeding in whom an endometrial polyp is diagnosed. Simple polypectomy is known to lead to subjective improvement in symptoms of bleeding and high satisfaction rates. However, no data exists where polypectomy is compared with expectant management prospectively.

Objective:

The primary objective of the proposed study is to answer the question whether endometrial polyps in women with postmenopausal bleeding should be treated when malignancy has been excluded.

Study-design:

A randomized controlled trial regarding resection of endometrial polyps in women with

postmenopausal bleeding.

Interventions:

Resection will take place in the same session in which the polyp is diagnosed. Resection is performed following standard procedures used in the residential hospital.

Comparative intervention:

In patients that are randomized for expectant management a sham resection procedure will be performed during 5 minutes.

Primary outcome measures:

The primary outcome measure is the recurrence of postmenopausal bleeding.

Analysis:

The primary end point will be recurrence of postmenopausal bleeding. Time to recurrence of postmenopausal bleeding will be assessed using Kaplan-Meier analysis.

In the intervention group and the control group, time to recurrence of postmenopausal bleeding will be compared using the Log Rank test.

The difference between the two groups will be made explicit by calculating a relative risk and 95% confidence interval. Complications, pain (measured on VAS-scale), quality of life and costs will be compared using the appropriate statistical tests.

Power calculation:

The recurrence of postmenopausal bleeding in case of an endometrial polyp is assumed to be 85% after 6 months.

In case a polyp is resected, we expect the probability of recurrence of bleeding to be 35%. In view of these assumptions, and using a two-sided test with conventional characteristics (alpha-error 5%, beta-error 20%), we need 60 patients to be randomised to the two arms of the study.

Doel van het onderzoek

Resection of endometrial polyp(s) in women with postmenopausal bleeding and endometrial thickness of more than 4 mm will lead to less recurrent bleeding than in women in whom no resection is performed.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Resection will take place in the same session in which the polyp is diagnosed.

Resection is performed following standard procedures used in the residential hospital.

Resection of endometrial polyp is performed by the hysteroscopist using the instruments of his/her choice.

- In general smaller polyps (< 5 mm) will be resected using mechanical instruments.
- Larger polyps will be resected using electrosurgical material, i.e. the monopolar polypsnare in or the bipolar electrode.

The polyp is resected completely at its stalk. Resections can occur in more than one piece if necessary.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Women with postmenopausal bleeding and endometrial thickness of more than 4 mm in whom an endometrial polyp is diagnosed during hysteroscopy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Women with postmenopausal bleeding on tamoxifen treatment.

Women with postmenopausal bleeding with (suspicion of) malignancy during hysteroscopy.

Onderzoeksopzet

Opzet

| | |
|------------------|-----------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blinding: | Enkelblind |
| Controle: | Placebo |

Deelname

| | |
|-------------------------|-----------------------|
| Nederland | |
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-09-2005 |
| Aantal proefpersonen: | 60 |
| Type: | Werkelijke startdatum |

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 09-09-2005 |
| Soort: | Eerste indiening |

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 | NL264 |
| NTR-old | NTR302 |
| Ander register | : N/A |
| ISRCTN | ISRCTN73825127 |

Resultaten

Samenvatting resultaten

N/A