

Randomised controlled Trial of Treatment of endometrial Polyps in case of post-menopausal bleeding

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 23/10/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR302

Study information

Scientific Title

Randomised controlled Trial of Treatment of endometrial Polyps in case of post-menopausal bleeding

Acronym

RaTTeP

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee

Study design

Multicentre randomised single-blind placebo-controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Endometrial polyps, post-menopausal 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. Resection of endometrial polyp is performed by the hysteroscopist using the instruments of his/her choice. In general smaller polyps (less than 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.

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

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Recurrence of post-menopausal bleeding

Secondary outcome measures

1. Quality of life will be assessed using several standard self-administered psychometric measures with established reliability and validity:

1.1. 36-item Short Form Health Survey (SF-36)

1.2. State Trait Anxiety Score (STAI)

2. Patient satisfaction will be assessed using a Visual Analogue Scale (VAS) score

Overall study start date

01/09/2005

Completion date

01/09/2007

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

60

Key exclusion criteria

1. Women with post-menopausal bleeding on tamoxifen treatment

2. Women with post-menopausal bleeding with (suspicion of) malignancy during hysteroscopy

Date of first enrolment

01/09/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Markstraat 42

Utrecht

Netherlands

3582 KM

Sponsor information

Organisation

St. Antonius Hospital (Netherlands)

Sponsor details

P.O. Box 2500

Nieuwegein

Netherlands

3430 EM

Sponsor type

Hospital/treatment centre

Website

<http://www.antonius.net/>

ROR

<https://ror.org/01jvpb595>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	report	01/09/2009	23/10/2020	Yes	No