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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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