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Can we predict the risk of cancer or precancer in postmenopausal women with polyps in their womb?

Submission date
24/05/2020

Recruitment status
No longer recruiting

Registration date
24/06/2020

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Polyps (soft growths) within the endometrium (lining of the womb) are commonly found in women who present with abnormal vaginal bleeding or incidentally when unrelated symptoms are investigated. It is not yet clear whether all polyps should be removed by surgery in postmenopausal women. The risk of underlying cancer or pre-cancer in these polyps varies depending on a number of risk factors. The main aim of this study was to identify risk factors in order to predict cancer or pre-cancer in postmenopausal polyps.

Who can participate?
All postmenopausal women diagnosed with polyps in their womb who are not already known to have womb cancer or pre-cancer, not taking tamoxifen medication, and chose to have their polyp removed surgically.

What does the study involve?
Women with polyps are asked to answer a number of questions about their relevant medical history and they also undergo a transvaginal ultrasound scan to record information about their polyps.

What are the possible benefits and risks of participating?
There may not be any direct benefits to women. However, their participation may benefit women in the future who are considering whether to have their polyps removed or not. There is no specific risk to women who participate in our study except it is a requirement to undergo a transvaginal ultrasound examination.

Where is the study run from?
Department of Obstetrics and Gynaecology, University College London Hospitals, UK.

When is the study starting and how long is it expected to run for?
October 2015 to September 2018

Who is funding the study?
University College London (UCL) Hospitals (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
102015

Study information

Scientific Title
Risk of premalignancy or malignancy in postmenopausal endometrial polyps: a CHAID decision tree analysis

Study objectives
It is hypothesized that patient characteristics and polyp morphological features on ultrasound can be used to predict the risk of premalignancy or malignancy in postmenopausal women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This was an observational study with no change to routine clinical practice and therefore full ethics approval or written patient consent was deemed not necessary, according to the HRA's online decision tool.

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Endometrial polyps

Interventions

This was an observational study only. Consecutive postmenopausal women referred by their general practitioners to the outpatient gynaecology unit were potentially eligible. All women had a routine transvaginal ultrasound examination. If an endometrial polyp is diagnosed on ultrasound, the polyp's morphological features are recorded, as well as the relevant medical information about the patient. Women who chose to have surgical management of their polyps were included in the statistical analysis.

Intervention Type
Procedure/Surgery

Primary outcome measure
Presence or absence of premalignancy or malignancy in endometrial polyps diagnosed using transvaginal ultrasound at baseline scan

Secondary outcome measures
Risk factors for premalignancy or malignancy in endometrial polyps were taken from the patient's medical records at the time of their clinical assessment. Patient characteristics and ultrasound morphological features were then analysed after the researchers had obtained histological diagnoses of the polyps in order to identify predictive risk factors.

Overall study start date
02/03/2015

Completion date
02/10/2018

Eligibility

Key inclusion criteria
1. Postmenopausal
2. Aged 45 years or above
3. At least 1 year history of amenorrhea
4. Diagnosed with endometrial polyps on transvaginal ultrasound and underwent hysteroscopic polypectomy or hysterectomy within 2 months of the diagnosis

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
At least 200 women

Total final enrolment
240

Key exclusion criteria
1. Hysterectomy
2. Known endometrial hyperplasia or cancer
3. Use of tamoxifen

Date of first enrolment
07/10/2015

Date of final enrolment
02/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals
Gynaecology Diagnostic and Treatment Unit
235 Euston Road
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Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.uclh.nhs.uk/Pages/home.aspx

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Foundation Trust

Alternative Name(s)
University College London Hospitals, UCLH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/06/2021	04/03/2022	Yes	No