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Developing tests for endometrial cancer detection

Submission date 02/08/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/08/2018	**Overall study status** Completed	
Last Edited 11/04/2023	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-test-for-womb-cancer-detect

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R04415

Study information

Scientific Title
DEveloping Tests for Endometrial Cancer deTection

Acronym
DETECT Multicentre

Study objectives
The aim of the study is to establish the diagnostic test accuracy of urogenital cytology for endometrial cancer detection in women with unexplained postmenopausal bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester West Research Ethics Committee, 27/06/2018, ref: 16/NW/0660

Study design
Prospective multicentre double-blind diagnostic test accuracy study

Primary study design
Observational

Secondary study design
Diagnostic test accuracy study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
After written informed consent, the trialists will obtain medical history and matched urine and vaginal samples from women with unexplained postmenopausal bleeding. Urine samples will be self collected in a sterile pot and vaginal samples will be taken by a research practitioner using a Delphi screener according to a strict protocol. The urine and vaginal samples will then be transferred to the cytopathology department at Manchester University NHS Foundation Trust for cytological assessment. The accuracy of urogenital cytology will be measured against standard diagnostic tests for endometrial cancer.

Intervention Type
Other

Primary outcome measure
Sensitivity: the proportion of women who have endometrial cancer who test positive by urogenital cytology (true positive rate) and negative predictive value – the proportion of test negatives who are true negatives. The accuracy of urine +/- vaginal cytology (index test) will be defined by the results of standard endometrial cancer diagnostic tests

Secondary outcome measures
1. Specificity: the proportion of women who do not have endometrial cancer who test negative by urogenital cytology (true negative rate)
2. False positive/negative rates (including clinical scenarios associated with these)
3. Positive predictive value
4. Test acceptability (short questionnaire to compare acceptability of urogenital cytology with standard diagnostic tests)

Exploratory analyses beyond the scope of this study:
The trialists will collect the residual urogenital cytology samples and store them in the MFT Biobank for future biomarker discovery work. They will centrifuge the samples to pellet the cellular material and freeze the pellet plus an aliquot of the supernatant.

Overall study start date
07/06/2018

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Women with unexplained postmenopausal bleeding attending for urgent investigations to exclude endometrial cancer
2. Written informed consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
2000

Total final enrolment
1890

Key exclusion criteria
Current exclusion criteria as of 21/12/2018:
1. Abnormal bleeding before the menopause (in whom the risk of cancer is much lower)
2. Previous diagnosis of endometrial cancer
3. Previous hysterectomy
4. Mirena coil in situ or removed within the last 3 months
5. Any other condition that would compromise participant safety or data integrity

Previous exclusion criteria:
1. Abnormal bleeding before the menopause (in whom the risk of cancer is much lower)
2. Previous diagnosis of endometrial cancer
3. Previous hysterectomy

Date of first enrolment
03/09/2018

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
Royal Oldham Hospital
Rochdale Road
Manchester
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OL1 2JH

Study participating centre
North Manchester General Hospital
Delaunays Road
Crumpsall
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M8 5RB

Study participating centre
Tameside General Hospital
Fountain Street
Ashton under Lyne
United Kingdom
OL6 9RW

Study participating centre
Wythenshawe Hospital
Southmoor Road
Manchester
United Kingdom
M23 9LT

Study participating centre
Trafford General Hospital
Moorside Road

Davyhulme
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M41 5SL

Sponsor information

Organisation
Manchester University Hospital NHS Foundation Trust

Sponsor details
St Mary's Hospital
Oxford Road
Manchester
England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
The Jon Moulton Charity Trust

Results and Publications

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

Intention to publish date
01/10/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Emma Crosbie (emma.crosbie@manchester.ac.uk). The consent form was adapted to include a specific clause to share anonymised data. Early versions may not include this.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/07/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No