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A comparison of the accuracies of ultrasound and magnetic resonance imaging in assessing the spread of womb cancer

Submission date	Recruitment status	[_] Prospectively registered
28/03/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/08/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2022	Cancer	

Plain English summary of protocol

Background and study aims
The spread of womb cancer is commonly estimated by an MRI scan before surgery, however, some studies reported that ultrasound could be as accurate as MRI. The potential benefits of ultrasound are its wider availability, lower cost and fewer contraindications compared to MRI. The aim of this study is to compare the accuracy of ultrasound and MRI in assessing the spread of womb cancer before surgery.

Who can participate?
All women with postmenopausal bleeding who are suspected of womb cancer on ultrasound in our clinic.

What does the study involve?
In women who are already undergoing transvaginal ultrasound assessment for postmenopausal bleeding, it involves having a simultaneous ultrasound assessment for the spread of womb cancer. All women with a confirmed diagnosis of womb cancer on biopsy will also be invited for an MRI scan to assess the spread of cancer.

What are the possible benefits and risks of participating?
The potential benefit is that women will have both tests to assess the spread of their womb cancer.
The potential risks are discomfort and inconvenience of having both tests, as well as, the risks of false-positive and false-negative diagnoses on ultrasound and MRI.

Where is the study run from?
Gynaecology Diagnostic and Treatment Unit, University College London Hospitals, London, UK

When is the study starting and how long is it expected to run for?
May 2011 to October 2018

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

Who is the main contact?
Dr Michael Wong, michael.wong3@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Michael Wong

ORCID ID
https://orcid.org/0000-0002-2168-1111

Contact details
Gynaecology Diagnostic and Treatment Unit
235 Euston Road
London
United Kingdom
NW1 2BU
+44 (0)20 3456 7890
michael.wong3@nhs.net

Type(s)
Public

Contact name
Dr Michael Wong

Contact details
Gynaecology Diagnostic and Treatment Unit
235 Euston Road
London
United Kingdom
NW1 2BU
+44 (0)20 3456 7890
michael.wong3@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
10/0316

Study information

Scientific Title
A prospective comparison of the diagnostic accuracies of ultrasound and magnetic resonance imaging in preoperative staging of endometrial cancer

Study objectives
The diagnostic accuracy of ultrasound is comparable to MRI for the prediction of deep myometrial invasion and cervical stromal invasion in women with endometrial cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2011, Central London REC2 committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; londoncentral.rec@hra.nhs.uk), ref: 10/H0713/66

Study design
Single centre 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
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Preoperative diagnoses of deep myometrial invasion and cervical stromal invasion in women with endometrial cancer

Interventions
Consecutive women presenting with postmenopausal bleeding to our gynaecology outpatient clinic during the study period are potentially eligible.

Women who have previously undergone a hysterectomy or already diagnosed with gynaecological malignancy will be excluded.

All women will be assessed by a single clinical research fellow, who has undergone intensive training in early pregnancy and gynaecological ultrasound prior to the start of the study. He will assess for the presence of endometrial cancer based on ultrasound subjective pattern recognition. All women will be divided into the following groups: 1. suspected endometrial cancer, 2. benign endometrial polyps, 3. uniformly thickened endometrium, 4. atrophic endometrium, 5. unsatisfactory ultrasound assessment.

All women with an unsatisfactory transvaginal ultrasound assessment or an axial uterus will be offered a transrectal ultrasound scan, saline infusion sonography or outpatient/day-case hysteroscopy.

Women with suspected endometrial cancer will simultaneously undergo a subjective assessment for the depth of myometrial invasion (1. no myometrial invasion or <50% myometrial invasion of the entire myometrial thickness, 2. ≥50% myometrial thickness) and cervical stromal invasion (present or absent). An outpatient endometrial biopsy (pipelle) will then be taken after the ultrasound scan. Hysteroscopy will be offered to those who decline or failed with an outpatient endometrial biopsy.

All women with a histologically confirmed diagnosis of endometrial cancer will be advised to undergo a preoperative MRI to assess for the depth of myometrial invasion and cervical stromal invasion by an experienced consultant radiologist in gynaecological oncology. The radiologist involved will be blinded to the ultrasound findings and the presence or absence of DMI and CSI will be assessed subjectively. The standard MRI protocol will involves T2-weighted imaging (T2WI), dynamic T1-weighted gadolinium sequences (DCE-MRI) and diffusion-weighted imaging (DWI-MRI) with an apparent diffusion coefficient map.

Women with endometrial cancer will be managed by a consultant gynaecological oncologist who will not take part in the study and each woman's management will be discussed routinely at a multi-disciplinary team meeting.

The diagnostic accuracies of ultrasound and MRI for deep (≥50%) myometrial invasion and cervical stromal invasion will be compared with the final histology (hysterectomy) as the gold standard.

Intervention Type
Procedure/Surgery

Primary outcome measure
At a single time point:
The diagnostic accuracies of ultrasound and MRI for DMI and CSI in endometrial cancer
1. Sensitivity measured using the findings from the respective imaging test with histology as the reference standard.
2. Specificity measured using the findings from the respective imaging test with histology as the reference standard.
3. Positive likelihood ratio measured using the findings from the respective imaging test with histology as the reference standard.
4. Negative likelihood ratio measured using the findings from the respective imaging test with

histology as the reference standard.
5. Overall accuracy measured using the findings from the respective imaging test with histology as the reference standard.

Secondary outcome measures
At a single time point:
1. The accuracy of ultrasound subjective pattern recognition in diagnosing endometrial cancer (sensitivity, specificity, positive likelihood ratio, negative likelihood ratio and overall accuracy) measured using the findings on ultrasound scan with histology as the reference standard.
2. The number of unsatisfactory ultrasound assessments to diagnose and stage endometrial cancer amongst women with postmenopausal bleeding (as a proportion of the total number of women included in the study).
3. The efficacies of transrectal ultrasound scan and saline infusion sonography (as a proportion of the total number of unsatisfactory ultrasound assessments) measured using patient records.

Overall study start date
31/05/2011

Completion date
02/10/2018

Eligibility

Key inclusion criteria
1. Postmenopausal women (at least 45 years of age with at least 1 year of amenorrhea)
2. Presenting with postmenopausal bleeding, including women with unscheduled bleeding whilst on hormone replacement therapy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
49

Total final enrolment
51

Key exclusion criteria
1. Women with a previous history of hysterectomy
2. Women with a known diagnosis of gynaecological malignancy
3. Women who decline a transvaginal or transrectal ultrasound scan
4. Women who have a contraindication to MRI scan
5. Women who are managed expectantly (without hysterectomy) following a diagnosis of endometrial cancer

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
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

Sponsor details
235 Euston Road
London
England
United Kingdom
NW1 2BU
+44 (0)20 3456 7890
uclh.randd@nhs.net

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 high-impact peer-reviewed journal.

Intention to publish date
28/03/2022

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

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2022	12/04/2022	Yes	No