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Comparing an easy-to-use swab test and ultrasound for detection of womb cancer

Submission date 18/12/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/01/2026	**Overall study status** Ongoing	
Last Edited 07/01/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Womb cancer (also known as endometrial cancer) is a common type of cancer that affects the womb lining. The main symptom of womb cancer is abnormal vaginal bleeding. However, only a small proportion of women with abnormal bleeding have womb cancer. Unfortunately, there are challenges in diagnosing womb cancer early. Ultrasound scans are often not specific enough, leading to many women being referred for further invasive tests unnecessarily.
This study aims to compare the performance of the ultrasound scan and the WID®-easy test and to gather the information needed to support the introduction of the WID®-easy test throughout the NHS .

Who can participate?
Women with a uterus aged 45 years or over, referred to a hospital clinic for evaluation of abnormal uterine bleeding

What does the study involve?
Follow-up data collection will occur at 3 months and 12 months from enrolment. All women in the trial will also undergo standard of care , a ultrasound scan. At recruitment, women will be informed of the small possibility of needing a call-back on receipt of a positive WID-easy result, if further testing has not been indicated based on the ultrasound result, a letter will be sent explaining the test result and inviting them to attend an appointment for a hysteroscopy under general anaesthetic .
The participants will also be invited to complete an optional questionnaire about their experience of the test at the end of their pathway. Participants will also be offered an opportunity to provide further feedback in the form of 1:1 interviews.

What are the possible benefits and risks of participating?
The direct benefit of taking part in this study is that the WID®-easy test has the potential to detect any womb cancers that may be missed by ultrasound, which is the current standard test you would be offered for investigation of abnormal bleeding. With any diagnostic test, including ultrasound which is the current standard of care test, there is a small risk of getting a false result. If there is a false negative result, we anticipate the participant would continue to have symptoms and would return to clinic and be reassessed.

Where is the study run from?
University College London Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2026 to May 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
70601

National Institute for Health and Care Research (NIHR)
208557

Integrated Research Application System (IRAS)
357394

Study information

Scientific Title
Prospective, interventional cohort trial of WID-easy test performance for detection of womb cancer in women with abnormal uterine bleeding

Acronym
EASY - CARE

Study objectives
The primary objective is to test the following two hypotheses:
1. Non-inferiority of the relative true positive rate of the WID®-easy to Transvaginal Ultrasound Scan (TVUS)with a non-inferiority margin of 15%.
2. Superiority of the relative false positive rate of the WID®-easy to TVUS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2025, Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; Tel: not available; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0200

Study design
Non-randomized; Interventional; Design type: Diagnosis, Device

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
All eligible women will be invited to participate in the trial, with trial information sent to them with their clinic visit appointment letter. Enrolment will be done from the Urgent Suspected Cancer clinics at each clinical site and from in- patient wards.

For potential participants that are recruited as inpatients in the hospital, the team we give the the maximum possible time to consider participation and also allocate extra time to explain the trial as well as allow for more Q&A time.

As part of the standard of care a speculum examination will be performed and women who consent to participate in the trial will have a cervicovaginal sample for the WID-easy test taken at this time. After sample collection all women will be treated according to the current standard of care pathway and will have an ultrasound scan performed. Women with an abnormal ultrasound scan or a positive WID-easy test will be recommended to have an endometrial biopsy and/or hysteroscopy.

At recruitment, women will be informed of the small possibility of needing a call-back on receipt of a positive WID-easy result, if further testing has not been indicated based on the ultrasound result (and a hysteroscopy or outpatient biopsy has not already been arranged), a letter will be sent explaining the test result and inviting them to attend an appointment for a hysteroscopy under general anaesthetic.

A very small number of participants may have an inconclusive test e.g. due to insufficient sample , in which case the clinical team will also write to them explaining the result and inviting them back for a repeat test.

Women will be given £20 voucher for any additional visits that arise due to the trial that are outside of their standard of care visits.

Follow up data will be collected at 3 and 12 months after the baseline visit. Analyses of the data will be conducted at both timepoints.

Following the end of their pathway, the clinical team will send the participant an optional questionnaire that can be completed online or on paper to collect feedback on their journey and the test.

A small number of women who volunteer will also have an opportunity to take part in 1:1 interviews online conducted by the trial collaborators , UCL Partners who have expertise in Insights & Evaluation methodology work. The purpose of the interviews will be to collect detailed feedback on the patient pathway and the experience with the WID-easy test. Both the study questionnaire & topic guide for the 1:1 interviews will be co-designed with lived experience group members in the community.

Intervention Type
Other

Primary outcome(s)
Outcome positive and outcome negative participants at 3 months after WID®-easy testing. Outcome positives are defined as cases with histologically confirmed endometrial and/or cervical and/or tubal and/or ovarian cancer. Outcome negatives are defined as cases with (a) histology confirmed absence of any gynaecological cancer and (b) confirmed (imaging and/or histology) absence of gynaecological cancer.

Key secondary outcome(s))
Outcome positive and outcome negative participants at 12 months after WID®-easy testing. Outcome positives are defined as cases with histologically confirmed endometrial and/or cervical and/or tubal and/or ovarian cancer. Outcome negatives are defined as cases with (a)

histology confirmed absence of any gynaecological cancer and (b) confirmed (imaging and/or histology) absence of gynaecological cancer.

Completion date
31/05/2028

Eligibility

Key inclusion criteria
Women with a uterus aged 45 years or more referred for evaluation of abnormal uterine bleeding who are willing and able to provide written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
100 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Current pregnancy
2. Previous hysterectomy

Date of first enrolment
23/02/2026

Date of final enrolment
05/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospital
235 Euston Road
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Study participating centre
Royal Free Hospital
Pond Street
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Study participating centre
Barnet Hospital
Wellhouse Lane
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Study participating centre
North Middlesex Hospital
North Middlesex University Hospital, Sterling Way
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Sponsor information

Organisation
Sola Diagnostics UK Ltd

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the EASY-CARE trial will be available on reasonable request from Sola Diagnostics UK Limited (trial@sola-diagnostics.com). Data will be fully anonymised. Requests will be considered for scientifically sound proposals addressing questions in line with participant consent and ethical approvals. Access will be provided under a data-sharing agreement. Data will be available from 24 months after publication of the data from the 12 month data collection point for a minimum of 5 years.

IPD sharing plan summary
Available on request