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Study into the accuracy of a new non-invasive device (Endosure test, EndoSure, Inc) for the diagnosis of endometriosis (ADDEND study)

Submission date
15/12/2024

Recruitment status
No longer recruiting

Registration date
17/12/2024

Overall study status
Ongoing

Last Edited
25/11/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We are conducting a pilot study to test a new non-invasive device called the Endosure test, which aims to diagnose endometriosis without surgery. Endometriosis is a condition where tissue similar to the lining inside the uterus grows outside it, causing pain and other symptoms.

Who can participate?
We are looking for three groups of women to participate:
Women scheduled for laparoscopic surgery due to pelvic pain (suspected endometriosis).
Women scheduled for laparoscopic surgery for other non-cancerous conditions.
Healthy female volunteers with no pelvic pain.
Participants must be pre-menopausal, aged 18-50 years, have no previous surgical detection or treatment of endometriosis, and no known cancer. They must also be willing to follow certain pre-test requirements.

What does the study involve?
Participants will:
Attend an additional one-hour research clinic.
Confirm they have followed pre-test requirements.
Complete a pelvic pain questionnaire.
Undergo the Endosure test, which is performed by trained staff.
For those undergoing surgery, standardized images will be taken during the procedure. Eight weeks after surgery, they will return for another clinic visit to repeat the questionnaire and Endosure test.

What are the possible benefits and risks of participating?
There are no risks associated with participating in this study. The potential benefit is helping to validate a device that could diagnose endometriosis without the need for invasive surgery.

Where is the study run from?
Worcestershire Acute Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2024 to August 2027

Who is funding the study?
British Society for Gynaecology Endoscopy

Who is the main contact?
Donna Ghosh, donna.ghosh@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
346375

Protocol serial number
BSGE grant application ref 36

Study information

Scientific Title
Pilot study to investigate the Accuracy and potential clinical application of a non-invasive Diagnostic Device, EVG Clinical Decision Tool (Endosure test, EndoSure Inc), in the diagnosis and management of ENDometriosis (ADDEND Study)

Acronym
ADDEND

Study objectives
GIMA can be adopted as a non-invasive biomarker in NHS in UK with good diagnostic results.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/04/2025, London - City & East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048171; cityandeast.rec@hra.nhs.uk), ref: 25/LO/0341

Primary study design
Interventional

Study design
Interventional pilot study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Non Invasive diagnosis of endometriosis

Interventions
Study Arms and Methodology:

Study Arm 1: Suspected Endometriosis Patients
Treatment Given: Participants will undergo the Endosure test (EVG Clinical Decision Tool) before and 8 weeks after laparoscopic surgery.
Total Duration of Treatment and Follow-Up: 8 weeks post-surgery.

Study Arm 2: Surgical Control Group
Treatment Given: Participants will undergo the Endosure test before and 8 weeks after laparoscopic surgery for benign conditions (e.g., laparoscopic sterilisation, cystectomy, fertility procedures).
Total Duration of Treatment and Follow-Up: 8 weeks post-surgery.

Study Arm 3: Healthy Volunteers (Non-Surgical Control Group)
Treatment Given: Participants will undergo the Endosure test at baseline and 8 weeks later.
Total Duration of Treatment and Follow-Up: 8 weeks.

Summary of Procedures:

Pre-Test Requirements: All participants must omit opioid medication for 7 days and prokinetic or antispasmodic medication for 3 days before the test. They must also fast for 8 hours prior to the test.
Endosure Test: Conducted by trained staff, involving a standardized EVG with a water load satiety test (WLST).
Surgery (for Arms 1 and 2): Standardized laparoscopic procedures with captured operative images for later review.
Follow-Up: 8 weeks post-surgery or post-initial test, participants will repeat the Endosure test and complete a pain questionnaire.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Endosure

Primary outcome(s)
1. Presence of endometriosis is measured using Endosure test at baseline and 8 weeks post-surgery
2. Severity of endometriosis is measured using Endosure test at baseline and 8 weeks post-surgery
3. Absence of endometriosis is measured using Endosure test at baseline and 8 weeks post-surgery

Key secondary outcome(s)
1. Pain levels are measured using EHP-30 questionnaire at baseline and 8 weeks post-surgery
2. Gastrointestinal myoelectrical activity is measured using Electroviscerogram with WLST at baseline and 8 weeks post-surgery
3. Surgical confirmation of endometriosis is measured using laparoscopic images at baseline
4. Diagnostic accuracy is measured using comparison of Endosure test results with surgical findings at baseline and 8 weeks post-surgery
5. Sensitivity and specificity of Endosure test are measured using statistical analysis of test results at baseline and 8 weeks post-surgery
6. Patient adherence to pre-test requirements is measured using patient self-report at baseline
7. Patient satisfaction with diagnostic process is measured using patient feedback questionnaire at 8 weeks post-surgery

Completion date
01/08/2027

Eligibility

Key inclusion criteria
1. Ages 18 – 50 years
2. Acceptable to patient to omit:
2.1. opioid medication (eg. Codeine, Morphine, etc) 7 days before test
2.2. prokinetic or antispasmodic medication (eg. Erythromycin, Domperidone etc) 3 days before test

Participant type(s)
All, Employee, Health professional, Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Ages < 18 and > 50 years
2. Known malignant disease
3. Confirmed menopause
4. BMI > 35 kg/m²

Date of first enrolment
01/08/2025

Date of final enrolment
01/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
England
WR5 1DD

Sponsor information

Organisation
British Society For Gynaecological Endoscopy

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Worcestershire Acute NHS Hospital Trust

Results and Publications

Individual participant data (IPD) sharing plan
The data will be owned by The Worcestershire Endometriosis Research Group, who will analyse the data and prepare the final report. The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: donna.ghosh@nhs.net

IPD sharing plan summary
Available on request, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	26/11/2024	17/12/2024	No	Yes