

Investigation of the diagnostic accuracy of a new blood test for endometriosis, compared with the current gold standard surgery for diagnosis

Submission date 06/10/2020	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/11/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/12/2024	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Endometriosis is a disorder in which tissue similar to the tissue that forms the lining of the uterus grows outside of the uterine cavity. The study will assess whether a new blood test, called the 'Mitomic® Endometriosis Test' or MET™ for short, can diagnose endometriosis as effectively as the current procedure used for diagnosis, an operation called a laparoscopy. Endometriosis has similar symptoms to other diseases, so up to 50% of patients who have the operation find out they do not have endometriosis. The aim is to find out if the blood test could be used to confirm or rule out a diagnosis of endometriosis, without the patient needing an operation. On the other hand, being able to rule in endometriosis as a possibility in those patients who have symptoms will speed up their access to appropriate treatment and care.

Who can participate?

Female patients who have been referred for their first laparoscopy to diagnose suspected endometriosis

What does the study involve?

Participants will need to give an extra blood sample at their pre-operation visit and this will be sent away to a laboratory where it can be tested using the MET™. The laparoscopy operation will continue as normal - the operating clinician will provide details about the type and extent of endometriosis seen during the surgery. Participants will also be asked to complete a short questionnaire about their symptoms and to complete a recovery diary after their laparoscopy. The trial aims to include 600 patients who will be recruited across about 12 participating sites over about 1 year.

What are the possible benefits and risks of participating?

The data collected will show the capability of the MET™ at predicting the presence or absence of endometriosis, identifying endometriosis subtypes (primary peritoneal, endometrioma, deep infiltrating endometriosis) and stages of endometriosis (Stage 1, 2, 3, 4 and 1/2, 3/4). The data

will also determine if there is a correlation between the MET™ result and presenting symptom (s), hormone status, age at diagnosis and age of the first report of symptoms. This study is being sponsored and funded by MDNA Life Sciences who developed the MET and the data will be used to obtain a CE mark and shown to healthcare payers (the NHS) to demonstrate the effectiveness of the MET.

The benefits conferred by this study are purely altruistic - if the results lead to the inclusion of MET in the NHS diagnostic pathway for endometriosis, then future patients may be diagnosed more quickly and may not have to have invasive surgery where it will not benefit them. The physical risk to patients in participating is minimal due to the non-interventional design of the study. The only additional clinical step is the donation of a blood sample and as the patient will be having blood tests before their surgery the additional risk is considered minimal. No decision about the care of the patient will be made based on the MET results so participation in the study will have no effect on the treatment.

Where is the study run from?
MDNA Life Sciences (USA)

When is the study starting and how long is it expected to run for?
January 2020 to May 2027

Who is funding the study?
MDNA Life Sciences (USA)

Who is the main contact?
Robert Poulter, r.poulter@mdnalifesciences.com

Contact information

Type(s)
Public

Contact name
Dr Robert Poulter

Contact details
Chief Business Officer
MDNA Life Sciences UK
The Biosphere
Newcastle Helix
Draymans Way
Newcastle upon Tyne
United Kingdom
NE4 5BX
+1 844-321-6362
r.poulter@mdnalifesciences.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

278047

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TF020-CIP1, IRAS 278047

Study information

Scientific Title

Investigation of the diagnostic accuracy of the Mitomic® Endometriosis Test (MET™) – real world evidence in the NHS

Acronym

DAMET-RWE

Study objectives

The Mitomic Endometriosis Test (MET™) is as good at diagnosing endometriosis as a laparoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending

Study design

Multicentre non-interventional real-world evidence study

Primary study design

Observational

Secondary study design

Diagnostic accuracy study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Endometriosis

Interventions

Patients who are being referred for a diagnostic laparoscopy for suspected endometriosis will also have a blood test using MET and the results will be compared. The results of the MET will not contribute to future decisions regarding the patient's care.

Intervention Type

Other

Primary outcome measure

The diagnostic accuracy of the Mitomic® Endometriosis Test (MET™), assessed by comparing the test results with the results of a laparoscopy (current standard of care), measured at a single timepoint

Secondary outcome measures

Measured at a single timepoint:

1. The diagnostic accuracy of MET™ for:

1.1. Different endometriosis subtypes (primary peritoneal, endometrioma, deep infiltrating endometriosis)

1.2. Different stages of endometriosis (Stage 1, 2, 3, 4 and 1/2, 3/4)

Assessed by comparing the MET results with the results from the laparoscopy.

2. Correlations between MET™ result and

2.1. Presenting symptom(s) assessed using patient questionnaire

2.2. Hormone status assessed using patient questionnaire

2.3. Age at diagnosis assessed using patient questionnaire

2.4. Age of first report of symptom assessed using patient questionnaire

3. The impact of laparoscopic surgery on quality of life measured using a patient diary in the immediate postoperative period

Overall study start date

01/01/2020

Completion date

01/05/2027

Eligibility

Key inclusion criteria

1. Female between menarche and menopause who are scheduled to undergo their first laparoscopic procedure for suspected endometriosis

2. Willing and able to provide an additional blood sample via venepuncture prior to the surgical procedure or administration of any presurgical medications (e.g. at the time of routine pre-operative bloods being taken and in all cases before the start of administering general anaesthesia)

3. Fit to undergo all procedures listed in protocol

4. Able to provide written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

600

Key exclusion criteria

1. A prior surgical diagnosis of endometriosis
2. Any contraindication to laparoscopy under general anaesthesia
3. Taking antibiotics or have taken antibiotics in the last 2 weeks

Date of first enrolment

01/01/2026

Date of final enrolment

01/01/2027

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre

Birmingham Women's Hospital

Mindelsohn Way

Birmingham

United Kingdom

B15 2TG

Study participating centre

Colchester General Hospital

Abbey Wing

St Peters Hospital

Guildford Road

Colchester

United Kingdom

KT16 0PZ

Study participating centre
Burnley General Teaching Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
University College Hospital
Elizabeth Garrett Anderson Wing
University College Hospital
25 Grafton Way
Fitzrovia
London
United Kingdom
WC1E 6DB

Study participating centre
Southmead Hospital
Redland Hill
Redland
Durdham Down
Bristol
United Kingdom
BS6 6UT

Study participating centre
Hampshire Endometriosis Centre
Princess Anne Hospital
University Hospital Southampton
Coxford Rd
Southampton
United Kingdom
SO16 5YA

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Rd
Glasgow
United Kingdom
G51 4TF

Study participating centre
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
University Hospital Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Liverpool Women's NHS Foundation Trust
Crown Street
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation

MDNA Life Sciences

Sponsor details

2054 Vista Parkway

Suite 400

West Palm Beach

United States of America

FL 33411

+1 (0) 844 321 662

j.creed@mdnalifesciences.com

Sponsor type

Industry

Website

<https://mdnalifesciences.com/>

Funder(s)**Funder type**

Industry

Funder Name

MDNA Life Sciences

Results and Publications**Publication and dissemination plan**

Planned publication of results in a suitable peer-reviewed journal. No other documents will be available.

Results will not be shared with participants directly - patients will receive their laparoscopy results and positive or negative diagnosis for endometriosis in line with normal clinical practice. The MET results will likely not be available until after the diagnosis has been made and as such will not be of use to the clinician or patient.

Intention to publish date

01/05/2028

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

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?
Participant information sheet	version V1.0	28/08/2020	05/11/2020	No	Yes