

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

<b>Submission date</b> 06/10/2020	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/12/2024	<b>Condition category</b> 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?
<a href="#">Participant information sheet</a>	version V1.0	28/08/2020	05/11/2020	No	Yes