A clinical trial to investigate the diagnostic accuracy of the Mitomic® Endometriosis Test (MET™) – Real World Evidence in the NHS (DAMET-RWE)

IRAS ID: 278047

We are inviting you to take part in a research study

- Please take time to read the following information carefully to decide whether or not you wish to take part. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your doctors in any way.
- You can stop taking part in the study at any time, without giving a reason.
- Ask if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. You will get a copy of that as well.

Important things that you need to know

- We want to investigate the diagnostic accuracy of a blood test called the 'Mitomic® Endometriosis Test' or MET™ for short.
- This means we will see if the MET™ can diagnose endometriosis with the same accuracy as the current diagnostic test: a laparoscopy, which is the procedure you are having.
- Your treatment will not change in any way, but an extra blood sample will be taken during the normal pre-operative procedure and you will be asked to fill in a questionnaire about your symptoms. This should only add about 30 minutes to your appointment.
- You will receive a patient diary, which will ask some questions about how you feel during your recovery.

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If you have any questions about this study, please talk to your hospital medical team.

You can contact Aspire Pharma for more information at clinicaltrials@aspirepharma.co.uk or aspirepharma.co.uk.

1 Why are we doing this study?

This study will assess if 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, a laparoscopy. We aim to find out if the blood test could be used to confirm or rule out a diagnosis of endometriosis before the patient needs an operation.

What is endometriosis?

Endometriosis is the name given to the condition where cells like the ones in the lining of the womb (uterus) are found elsewhere in the body.

Each month these cells react in the same way to those in the womb, building up and then breaking down and bleeding. Unlike the cells in the womb that leave the body as a period, this blood has no way to escape. This can have severe effects which impact on a woman's life such as: severe pain, lack of energy, depression and difficulty having a baby (infertility).

If you want to know more about endometriosis, talk to your doctor or nurse.

How is endometriosis usually diagnosed?

The only way to be certain that you have endometriosis is to have a laparoscopy, which is an operation in which a camera (a laparoscope) is inserted into the pelvis via a small cut near the navel. The surgeon uses the camera to see the pelvic organs and look for signs of endometriosis. You will be put to sleep (have a general anaesthetic) for this procedure.

What are we trying to find out?

MET™ has already been studied in a small population of patients, in which the test detected 80% of patients with endometriosis and indicated 35% might have endometriosis who after laparoscopy were confirmed to not have the condition. We are trying to confirm whether MET™ is effective at diagnosing endometriosis compared with laparoscopy.

We will also use the results from your questionnaire to see if the results of the MET™ can be correlated with the signs of your illness or type of disease.

Your input into the study will help us to confirm the outcomes and could help make the test widely available to patients through the NHS in the future.

2 Why am I being asked to take part?

You are being asked to take part as your doctor has referred you to have a laparoscopy for suspected endometriosis. If you agree to take part in the trial, you will have this procedure as normal, but your blood will also be tested using MET™ and the results will be compared.

3 What do I need to know about the blood test in this study?

The test is looking for specific DNA deletions that are associated with endometriosis, which are circulating in your blood. Extracted blood is sent to an external laboratory, where the DNA is extracted and is amplified to a detectable level.

The test gives a simple 'positive' or 'negative' for endometriosis based on a cut-off point for the deletion level in the blood.

4 What will I need to do if I take part?

If you agree to take part in this study, you will need to fill in a questionnaire about your symptoms and about any hormone treatments you have taken in the past. Extra blood samples will be taken during your pre-operative blood tests.

After your surgery, you will be given diary that contains 9 questions about your recovery to fill in once per week for 6 weeks. The questions are answered by ticking 'Yes' or 'No' and ticking how you feel on a scale from 1 to 5. After 6 weeks you can post the diary to the trial organisers using the stamped, addressed envelope provided. If you do not complete the diary, the results from your questionnaire and laparoscopy surgery will still be used, unless you withdraw your consent.

Can I definitely take part?

Not everyone can take part in this study. You will be asked some questions to see if you are able to take part.

What if the questions show I can take part?

If these questions show you can take part and you agree to join the study, we will ask you to sign a consent form so that we can use the answers you give in the questionnaire and the results from both your laparoscopy and blood test. Your personal data will not be shared outside of this trial and all results will be anonymised.

What will happen to me during the study?

This study is not an interventional study, which means your treatment/ diagnosis will not be impacted by the results of the test. The blood sample will likely not be tested prior to the results from your laparoscopic procedure, and therefore, MET™ will not provide any additional information above your diagnostic procedure.

What happens to my blood sample?

Your blood sample will be sent to a laboratory for testing. The sample will only be identified by the Patient Identification Number that will be assigned to you if you enrol and a barcode number on the sample tube. No personal data will be associated with the sample, so the staff at the laboratory will not know who the sample came from or whether you were diagnosed with endometriosis.

Once the blood sample has been tested, it will be destroyed, unless you consent for it to be kept for use in other research. If you do, your sample and anonymous clinical and pathology information will be retained for up to 10 years for use in other studies by MDNA Life Sciences to develop and validate improved diagnostic tests for human disease. You are not required to agree to this future research use to participate in the DAMET-RWE trial and can withdraw your participation at any time.

5 What are the possible side effects?

You are unlikely to experience any additional side effects (other than those described by your physician associated with the other procedures you are undergoing) from taking

part in this trial, because no extra procedures are carried out other than those that are normal for a laparoscopy. An extra blood sample will be taken, but you will need to have blood tests before your laparoscopy regardless of whether you choose to take part in this trial.

The potential discomforts that may be expected include fainting or light-headedness which can sometimes occur during or after blood draw procedures. These effects last only a few minutes and since only a small volume of blood will be drawn, the risk of this occurring is very minimal. Also, very rarely slight swelling, bruising or bleeding occur in the pricked area. Proper care and hygiene offered by the trained and qualified staff will minimize any discomfort and possibility of infection.

6 What are the possible benefits of taking part in this study?

By taking part in this study, you will help us to confirm if the MET™ is effective in diagnosing endometriosis. You will also help us to generate data which can be used to support uptake in the NHS. While there is no immediate benefit to you, as you are already undergoing laparoscopy, this could mean that in the future, women can have a blood test to diagnose or rule out endometriosis, instead of having an operation under general anaesthetic, which has known side effects. The MET™ could help inform clinicians when an operation will be most effective. This could mean that some women receive a quicker endometriosis diagnosis.

7 What are the possible disadvantages and risks of taking part?

Regardless of your choice to participate, the procedures and treatments you go through will remain unchanged, therefore there is no additional risk to you above that which has been described to you by your physician for laparoscopic surgery. If you choose to participate, your appointment might take a bit longer and you will need to give an extra blood sample.

8 More information about taking part

Do I have to take part in the study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

A decision to not take part at any time will not affect the standard of care you receive.

Will I get paid for my participation in this study?

No, patients will not receive any financial incentives to participate in this study.

Can I stop taking part after I've joined the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. However, we would advise that you talk to your study doctor or nurse

first. They can advise you about any concerns you may have.

A decision to stop taking part at any time will not affect the standard of care you receive.

What will happen to the results of the study?

When the study is completed, a summary of the anonymised results will likely be published in medical journals and/or documents for assessment by the authorities.

You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

Who is organising and funding the study?

The study is a multi-centre study, which means that several sites are participating.

This study is organised by the Contract Research Organisation (CRO), Aspire Pharma Ltd, in association with MDNA Life Sciences Inc. MDNA Life Sciences Inc. are the legal manufacturer of the MET kit and the sponsors of the trial. The study coordination, data collection and analysis will be completed by Aspire Pharma Ltd and/or MDNA Life Sciences Inc.

Your doctor is not receiving any money or other payment for asking you to be part of the study.

MDNA Life Sciences Inc have overall responsibility for the conduct of the study. They are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

Who has reviewed the study?

The study has been reviewed by clinicians and scientists in the UK.

It has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA), as well as by a Research Ethics Committee and the hospital's Research and Development Office.

What if something goes wrong for me?

If you have any concerns about the way you have been approached or treated during the study, please talk to your study doctor or nurse. If you are still unhappy, or if you wish to complain, please use the NHS complaints process. The Patient Advice and Liaison Service (PALS) offers confidential advice, support and information on health-related matters. You can find officers from PALS in your local hospital.

If you are harmed by taking part in the study, or if you are harmed because of someone's negligence, then you may be able to take legal action.

If you need to report any side effects or are feeling unwell, please contact the 24 hour contact number: <add site specific contact details>.

9 Data Retention and Transparency

What will happen to information about me collected during the study?

The information that you give and/or your medical records will be used in order to undertake this study and Aspire Pharma/MDNA Life Sciences will act as the data controller for this study. This means that

we are responsible for looking after your information and using it properly. Your personal information will not be shared with the sponsor or the CRO, but will be kept securely at the hospital where you were recruited for 10 years after the study has finished, in line with the NHS Records Management Code of Practice 2016.

The data generated as part of this study will be retained by the sponsor in an anonymised format.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information or by contacting medinfo@aspirepharma.co.uk.

If you agree to take part in this study, your doctor will collect information about you, your endometriosis symptoms and your progress which will be analysed by the researchers. Your hospital notes may also be looked at by the hospital staff if necessary.

We will follow all legal requirements to make sure that all information about you is treated appropriately, ethically and in line with EU General Data Protection Regulation 2016/679.

Information held, for example by the NHS, may be used to provide information about your health status after participation in the trial. There is a question about this on the consent form that we will ask you to sign before you begin the study. We would keep this information separate from other information we collect about you.

10 Contacts for further information

If you want further information about the study, contact your If you have any questions please speak to your hospital medical team.

Thank you for taking the time to consider taking part in this study.