

# Development of a blood test for uterine sarcoma - diagnosis

<b>Submission date</b> 06/05/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/06/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/02/2026	<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

Uterine sarcomas account for 3 in 100 of cancers arising from the uterus, or womb. They can be difficult to diagnose since they have many of the same symptoms and scan features as uterine fibroids, and biopsy from the womb lining (endometrium) only detects a third of cases. At present there is no blood test that can be used to guide patients and their doctors in diagnosing uterine sarcomas. Circulating tumour DNA (ctDNA) is fragments of cancer released from cancer cells that can be detected within the blood and can be used to diagnose and monitor cancers. The genetic profile of uterine sarcomas is complex, and designing a ctDNA-based blood test to diagnose uterine sarcomas needs to take these complexities into account, and to ensure that there is a clear difference from the profile of fibroids. This project aims to pilot the use of a ctDNA-based test to help identify patients who have or do not have a uterine sarcoma.

### Who can participate?

Patients aged 18-99 years who are due to undergo surgery for a large fibroid or suspected to have a uterine sarcoma

### What does the study involve?

We will collect information from investigations that are performed before surgery, including scan images (ultrasound/magnetic resonance imaging (MRI)/computer tomography (CT) /positron emission tomography (PET) MRI/CT/PET scans), blood test results, and biopsies from the endometrium (womb lining). A sample of blood will be taken before the planned surgery for ctDNA analysis and compared with the outcome from surgery. A number of participants will also be invited to take part in an interview to discuss their experiences in the study and their views on the potential for a blood test to diagnose uterine sarcomas.

### What are the possible benefits and risks of participating?

It is unlikely that participants will receive any direct benefit from taking part in this study. However, it is hoped that the results of this research study could potentially benefit other patients with a suspected uterine sarcoma in the future.

Where is the study run from?  
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?  
April 2025 to March 2028

Who is funding the study?  
The Eve Appeal (UK)

Who is the main contact?  
Dr Esther Moss, leicestergcrg@le.ac.uk

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Esther Moss

### ORCID ID

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

350809

### Protocol serial number

CPMS 65318

## Study information

### Scientific Title

Development of a bLOOdstest for uteRine Sarcoma - Diagnosis (DOORS-D)

### Acronym

DOORS-D

### **Study objectives**

To investigate whether genomic alterations in plasma are able to distinguish between uterine sarcomas and uterine fibroids

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 13/05/2025, South Central - Berkshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8029; berkshireb.rec@hra.nhs.uk), ref: 25/SC/0107

### **Study design**

Single-centre observational cohort study

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Uterine sarcomas and uterine fibroids

### **Interventions**

Development of a blood test to improve the diagnostic process

This project aims to pilot the use of a ctDNA-based test to help identify patients who have or do not have a uterine sarcoma. We will recruit patients who are due to undergo surgery for a large fibroid or suspected of having a uterine sarcoma. We will collect information from investigations that are performed before surgery, including scan images (ultrasound/magnetic resonance imaging (MRI)/computer tomography (CT)/positron emission tomography (PET) MRI/CT/PET scans), blood test results, and biopsies from the endometrium (womb lining). A sample of blood will be taken before the planned surgery for ctDNA analysis and compared with the outcome from surgery. A number of participants will also be invited to take part in an interview to discuss their experiences in the study and their views on the potential for a blood test to diagnose uterine sarcomas.

### **Intervention Type**

Genetic

### **Primary outcome(s)**

Identification of uterine sarcomas by genomic testing of plasma pre-operatively

### **Key secondary outcome(s))**

1. Genomic profile of sarcomas and fibroids measured using biopsies taken from hysterectomy or myomectomy specimens
2. Sensitivity/specificity of the ctDNA test to diagnose uterine sarcomas in the pre-operative blood sample

3. Sensitivity/specificity of an expert radiologist versus AI to diagnose uterine sarcomas from pre-operative CT/MRI/PET imaging
4. Psychological impact of ctDNA testing in US diagnosis measured using qualitative interviews at 1-6 months following hysterectomy/myomectomy

**Completion date**

01/03/2028

## Eligibility

**Key inclusion criteria**

1. Due to undergo surgery (hysterectomy or myomectomy) for a suspected uterine sarcoma or an abnormally appearing fibroid
2. Aged 18-99 years
3. Female
4. Willing and able to consent to participate in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

99 years

**Sex**

Female

**Total final enrolment**

0

**Key exclusion criteria**

1. Not undergoing surgery (hysterectomy or myomectomy) for a suspected uterine sarcoma or abnormal appearance fibroid
2. Male
3. Not willing and able to consent to participate in the trial
4. Unable to understand the study requirements despite interpreter support

**Date of first enrolment**

01/07/2025

**Date of final enrolment**

01/03/2028

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**University Hospitals of Leicester NHS Trust**

Leicester Royal Infirmary

Infirmery Square

Leicester

England

LE1 5WW

## Sponsor information

### Organisation

University of Leicester

### ROR

<https://ror.org/04h699437>

## Funder(s)

### Funder type

Charity

### Funder Name

The Eve Appeal

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol article</a>		17/02/2026	18/02/2026	Yes	No
<a href="#">Participant information sheet</a>	version 2	22/04/2025	02/06/2025	No	Yes