

Development of a bloodtest for uterine sarcoma monitoring

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| Submission date 06/05/2025 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 04/06/2025 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 16/07/2025 | Condition category Cancer | <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 are a rare type of cancer that occur in the uterus (womb). They are hard to diagnose because they share many symptoms with non-cancerous growths called fibroids. Currently, there is no blood test to help doctors monitor these cancers or detect if they come back. This study aims to develop a blood test that can detect fragments of cancer DNA in the blood to monitor uterine sarcomas.

Who can participate?

Patients who have been diagnosed with a uterine sarcoma and are under follow-up care can participate in this study.

What does the study involve?

Participants will have blood samples taken every 3 months. These samples will be analyzed to see if the new blood test can detect the return of uterine sarcoma. The study will also collect information from participants' medical records, including scan images and genetic analysis of their tumors.

What are the possible benefits and risks of participating?

Participants will not receive any direct benefits from taking part in this study. However, the results could help improve monitoring and treatment for future patients with uterine sarcoma. There are no significant risks involved in participating, but taking blood samples may cause minor discomfort.

Where is the study run from?

University of Leicester (UK)

When is the study starting and how long is it expected to run for?

April 2025 to April 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

EudraCT/CTIS number

Nil known

IRAS number

350807

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 65319

Study information

Scientific Title

Development of a bLOOdtest for uteRine Sarcoma – Monitoring (DOORS-M)

Acronym

DOORS-M

Study objectives

To identify a genomic or methylation signature that could be used within a ctDNA 'test' to monitor uterine sarcomas

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/05/2025, 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/0108

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Uterine sarcoma

Interventions

All participants will be asked questions about their demographics, medical and family history, and any symptoms. Additional information will be taken from their medical records, including information on medical, family and surgical history, the subtype of sarcoma and the pathology results. Information and images from any ultrasound, CT, MRI or PET scans that show the uterine sarcoma will also be collected. The original tumour biopsies will be reviewed by study team's pathologist who will provide a second opinion on the subtype of sarcoma. A small piece of tumour taken at primary surgery or biopsy will be analysed to confirm the type of uterine sarcoma and may undergo genetic (DNA) analysis. If the tumour has undergone genetic sequencing through the NHS genomic medicine service, there results will be requested.

Participants recruited at the University Hospitals of Leicester will be asked to give a blood sample (up to 20mls or 1.5 tablespoons) every 3 months, or each time they attend for a follow up appointment with the oncology team. If they are due to undergo chemotherapy treatment, they will be asked for a blood sample before each cycle of chemotherapy. If they are having radiotherapy or surgery, they will be asked for a blood sample before and after the course of treatment. At each follow-up visit the participants will be asked if they are having any symptoms, for example vaginal bleeding or pelvic pain. The results of any investigations to investigate suspected recurrence and/or response to chemotherapy/radiotherapy/surgery will be recorded along with any treatment that have been given for the uterine sarcoma. This will continue until the patient is discharged from follow up or the study finishes. The team will also obtain further information from the patients' medical records through the NHS for up to ten years. The blood tests will be analysed aiming to identify genetic markers that can detect and/or predict uterine

cancer recurrence. Participants and their doctors will not be informed of the result of the blood test.

Participants may 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 monitor uterine sarcomas. This will take approximately 1 hour and will take place over the telephone or online using Microsoft (MS) Teams. The anonymised views and experiences will be compared with other women who are taking part in this study and will be used to help the research team understand the patient's perspective.

Intervention Type

Genetic

Primary outcome measure

1. Body Mass Index (BMI) is measured using height and weight recorded with a stadiometer and calibrated scale at baseline (visit 1)
2. Uterine sarcoma diagnostic and treatment data are measured using clinical records review at baseline (visit 1)
3. Medical and family history is measured using patient interview and clinical records review at baseline (visit 1)
4. Symptom burden is measured using a symptom checklist questionnaire at baseline (visit 1) and approximately every 3 months
5. Circulating tumor DNA (ctDNA) presence is measured using a personalized, tumor-informed ctDNA assay (e.g. Signatera) from blood samples at baseline (visit 1) and approximately every 3 months

Secondary outcome measures

Patient experience of diagnosis, treatment, follow-up, and views on prognostic blood testing is measured using a semi-structured qualitative interview at any time following recruitment

Overall study start date

23/04/2025

Completion date

01/04/2028

Eligibility

Key inclusion criteria

1. Uterine sarcoma
2. Aged 18 years or older
3. Female

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

99 Years

Sex

Female

Target number of participants

50

Total final enrolment

50

Key exclusion criteria

1. Male
2. Under 18 years
3. Not previously undergone treatment for a uterine sarcoma

Date of first enrolment

01/07/2025

Date of final enrolment

28/03/2028

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary

Infirmary Square

Leicester

United Kingdom

LE1 5WW

Study participating centre

University Hospitals Bristol and Weston NHS Foundation Trust - Oxford Covid19 Trials

Medical Research Unit, B501

Bristol Royal Infirmary

Marlborough Street

Bristol
United Kingdom
BS2 8HW

Study participating centre
The Guys and Lewisham NHS Trust
Guys Hospital
St Thomas Street
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
University of Leicester

Sponsor details
University Road
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United Kingdom
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+44 116 3736508
RGOsponsor@le.ac.uk

Sponsor type
University/education

Website
<https://le.ac.uk>

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

Funder(s)

Funder type
Charity

Funder Name
The Eve Appeal

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journals

Intention to publish date

01/04/2028

Individual participant data (IPD) sharing plan

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 2 | 21/04/2025 | 04/06/2025 | No | Yes |