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Development of a bloodtest for uterine sarcoma monitoring

Submission date 06/05/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/06/2025	**Overall study status** Ongoing	
Last Edited 18/02/2026	**Condition category** Cancer	

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

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Additional identifiers

Integrated Research Application System (IRAS)
350807

Central Portfolio Management System (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

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s)
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

Completion date
01/04/2028

Eligibility

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

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
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
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
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
England
BS2 8HW

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

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/02/2026	18/02/2026	Yes	No
Participant information sheet	version 2	21/04/2025	04/06/2025	No	Yes