ISRCTN14800787 https://doi.org/10.1186/ISRCTN14800787

Development of a blood test for uterine sarcoma - diagnosis

Submission date	Recruitment status	[X] Prospectively registered
06/05/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/06/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/07/2025	Urological and Genital Diseases	[X] 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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
350809

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65318

Study information

Scientific Title

Development of a blOOdtest 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

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

Secondary outcome measures
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

Overall study start date
22/04/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Female

Target number of participants
50

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
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

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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 a peer-reviewed journal and at medical conferences.

Intention to publish date
01/03/2028

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?
Participant information sheet	version 2	22/04/2025	02/06/2025	No	Yes