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Description and study of the steroid Metabolome in mucinous ovarian cancer

Submission date 04/09/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/03/2026	**Overall study status** Ongoing	
Last Edited 17/03/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

We are conducting this research to find out new ways to diagnose a particular, extremely rare type of ovarian cancer – called mucinous ovarian cancer. We want to determine how well our new tests diagnose the disease. These tests could help current ovarian cancer patients as doctors need new ways to know how their patients respond during treatment.

We are conducting three studies:

1. Women who present with ovarian cysts / masses
2. Women who have already been treated for mucinous ovarian cancer
3. Women undergoing treatment for certain types of bowel cancer.

We are testing whether urine testing can be useful in monitoring them, and hope that testing for specific substances in the urine will help us find out more.

Our research is focused on investigating a range of biological molecules in human samples to find out if they are useful in diagnosing and treating ovarian cancer. It is difficult to find the exact source of some rare ovarian cancers during diagnostic testing, so we are also looking at the levels of specific biological substances in the urine of women with appendiceal cancer. We are also comparing results from ovarian cancer to those of appendiceal cancer as a control.

Who can participate?

Women over the age of 18 who have the capacity to give informed consent may be eligible to participate in the study if they belong to one of the following patient groups.

In Sub-Study 1, which focuses on diagnostics, participants include those undergoing surgery for adnexal masses, as well as those with a confirmed biopsy of mucinous ovarian cancer prior to the initiation of treatment.

Sub-Study 2 involves follow-up and includes participants who have received a confirmed histological biopsy diagnosis of primary mucinous ovarian cancer after completing first-line treatment.

Sub-Study 3 is concerned with appendiceal and pseudomyxoma peritonei cancers. Eligible participants include those with a pre-operative clinical radiological diagnosis of pseudomyxoma peritonei, as well as those with a confirmed histological diagnosis of low-grade appendiceal mucinous neoplasm (LAMN) or appendiceal carcinomas, excluding non-mucin-producing and neuroendocrine tumours.

What does the study involve?
A participant information sheet would be provided, and the study would be explained in detail. If the individual agrees to take part, they would sign a consent form and then complete a set of baseline questions, including details about their demographics and health conditions.

Participants would then be asked to collect all of their urine over a 24-hour period, at a time convenient to them, in their own home. A collection bottle would be supplied, and the sample would be retrieved at the participant's next hospital visit. Those enrolled in Sub-Studies 1 and 3 would be required to collect urine on a single occasion only. In contrast, participants in Sub-Study 2 would be asked to collect urine approximately every three months for a period of two years, with efforts made to align these collections with their routine clinic appointments.

What are the possible benefits and risks of participating?
Whilst there may be no direct benefit to participants, the information we get will tell us the different biomarkers that are present in the samples. We hope this may lead to a new test or treatment for ovarian cancer.

While we take every precaution to protect privacy, there is always a small risk to data confidentiality when participating in research. We have strict procedures in place to protect personal information, including secure storage systems and limited access to identifying information.

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

When is the study starting and how long is it expected to run for?
January 2024 to June 2029

Who is funding the study?
Eve Appeal (co-funder), and the Birmingham Women's and Children's Hospital Global Research Fund (co-funder).

Who is the main contact?
STEMOVA@contacts.bham.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
338830

Central Portfolio Management System (CPMS)
64298

Study information

Scientific Title
Characterisation of the STEroid Metabolome in mucinous OVArian cancer

Acronym
STEMOVA

Study objectives
1. Investigate urinary metabolome and other novel targets in women with mucinous carcinomas, mucinous borderline tumours, benign ovarian tumours, and mucinous appendiceal /pseudomyxoma peritonei tumours and other histology types of ovarian tumours
2. Investigate urinary steroids and other biomarkers in women undergoing follow-up with known mucinous ovarian cancer to characterise changes seen in women with recurrence
3. Investigate urinary steroids and other biomarkers in women undergoing surgery for specific types of appendiceal and pseudomyxoma peritonei cancer to identify key differences between these tumour types and mucinous ovarian cancer

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 12/05/2025, Bradford / Leeds REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 25/YH/0085

Primary study design
Observational

Study design
Prospective multi centre study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Mucinous ovarian cancer, mucinous appendiceal and pseudomyxoma peritonei cancer.

Interventions
Study 1
The first sub-study is a multicentre prospective study to investigate urinary steroid profiling in mucinous cancer, mucinous benign and borderline tumours. 265 individuals will be recruited in total.
24-hour urine samples will be collected from all recruited participants however, a subset of participants with confirmed mucinous histology type will be analysed and a subset of participants with confirmed other tumour types will be analysed. This is to reduce the costs involved in the experimental work and to maximise our chances of discovering and validating new biomarkers. Participants will be asked to collect all of their urine at a single timepoint in a 24-hour period in a bottle to be brought to their next hospital visit, which will be collected by the research team. Sample collection instructions will be provided to sites to standardise collection and processing of samples. A CRF will also be completed by the study team reporting demographics and medical history etc.

Study 2
The second sub-study will recruit 50 individuals with confirmed histological biopsy diagnosis of primary mucinous ovarian cancer after completion of first-line treatment.
Participants will be asked to collect all of their urine in a 24-hour period in a single bottle to be brought to their next hospital visit, which will be collected by the clinical care team or research nurses. Urine samples will be collected at three-month intervals to coincide with clinic visits over a two-year period, but some flexibility between two and six months is acceptable to undertake these visits. A CRF will also be completed by the study team at baseline visit only reporting demographics and medical history etc.

Study 3
The third sub-study will investigate urinary steroid profiling in mucinous appendiceal or pseudomyxoma peritonei cancer. 25 individuals will be recruited in total.
24-hour urine samples will be collected at a single time point from all recruited participants. Participants will be asked to collect all of their urine in a 24-hour period in a single bottle to be

brought to their next hospital visit, which will be collected by the clinical care team or research nurses. A CRF will also be completed by the study team reporting demographics and medical history etc.

Intervention Type
Other

Primary outcome(s)
Expression of steroidogenic genes, enzymes and metabolites from the ovaries. This will be measured from the output of 24 hour urine samples collected from patients.
For study 1 - The urinary steroid metabolome will be profiled via GC-MS and other technologies to determine the “steroid fingerprint” in MOC, MBT, and benign ovarian tumours.
For study 2 - The urinary steroid metabolome in confirmed MOC will be profiled via GC-MS and other technologies to determine if steroid profiles change during follow-up or at recurrence.
For study 3 - The urinary steroid metabolome will be profiled via GC-MS and other technologies to determine the “steroid fingerprint” in MOC, MBT, benign ovarian tumours, and mucinous appendiceal or pseudomyxoma peritoneal cancer.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/06/2029

Eligibility

Key inclusion criteria
Women over the age of 18 years with capacity to give informed consent and from the following patient groups:

Sub-Study 1 - Diagnostic:
1.1. Participants undergoing surgery for adnexal masses.
1.2. Participants with confirmed biopsy of mucinous ovarian cancer prior to start of treatment.

Sub-Study 2 – Follow-up:
2.1. Participants with a confirmed histological biopsy diagnosis of primary mucinous ovarian cancer after completion of first-line treatment.

Sub-Study 3 – Appendiceal/ pseudomyxoma peritonei Cancer
3.1. Participants with a pre-operative clinical radiological diagnosis of pseudomyxoma peritonei.
3.2. Participants with a confirmed histological diagnosis of low grade appendiceal mucinous neoplasm (LAMN) and appendiceal carcinomas (excluding non-mucin-producing and neuroendocrine tumours).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Sub-Study 1:
1.1. Participants lacking capacity to consent.
1.2. Using hormonal contraception / implant within last 3 months.
1.3. Used Hormone Replacement Therapy or GnRH analogues in last 3 months.
1.4. Used steroid treatment in last 3 months including inhalers.
1.5. Commenced chemotherapy treatment for ovarian carcinoma.
1.6. Undergoing delayed debulking surgery for ovarian cancer after chemotherapy.

Sub-Study 2:
2.1. Participants lacking capacity to consent.
2.2. Using hormonal contraception / implant in last 3 months.
2.3. Used HRT or GnRH analogues in last 3 months.
2.4. Used steroid treatment in last 3 months including inhalers.

Sub-Study 3:
3.1. Participants lacking capacity to consent.

Date of first enrolment
01/09/2025

Date of final enrolment
01/09/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre

University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
Cardiff ECMC
Cardiff University
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XN

Study participating centre
Hinchingbrooke Hospital (hinchingbrooke Healthcare Trust)
Hinchingbrooke Park
Huntingdon
England
PE29 6NT

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
The Christie at Home
The Christie NHS Foundation Trust
The Palatine Centre
63-65 Palatine Road
Manchester
England
M20 3LJ

Study participating centre

University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

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

Study participating centre
Hammersmith Hospitals NHS Trust
Hammersmith Hospital
Du Cane Road
London
England
W12 0HS

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
Midland Metropolitan University Hos
Grove Lane
Smethwick
England
B66 2QT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Not defined

Funder Name
EVE Appeal

Funder Name
Birmingham Women's and Children's Hospital Global Research Fund

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 file	version 1.0	28/02/2025	05/09/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes