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The Salurate Study: Validation of salivary uric monitoring for early prediction of hypertensive (high blood pressure) disorders of pregnancy

Submission date
18/06/2024

Recruitment status
Recruiting

Registration date
08/07/2024

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Salurate study aims to validate a new method for monitoring uric acid levels in saliva to predict disorders of high blood pressure in pregnancy early. Hypertensive disorders, such as pre-eclampsia, are significant complications during pregnancy that can lead to severe health issues for both the mother and the baby. Early detection and management of these conditions are crucial for improving outcomes for both mum and baby. The study seeks to address current diagnostic limitations and enhance prenatal care by providing a non-invasive, easy-to-use tool for early risk assessment.

Who can participate?
The study targets pregnant women who meet specific inclusion criteria. Participants must be over 16 years old, less than 16 weeks pregnant with a singleton pregnancy and willing to provide saliva samples for testing. The exact inclusion and exclusion criteria are detailed in the protocol, ensuring that only eligible candidates are enrolled to maintain the study's integrity and reliability.

What does the study involve?
Participants in the Salurate study will undergo several steps:
1. Informed Consent: Before enrolling in the study, participants will be fully informed about the study's purpose, procedures, potential risks, and benefits. They will then sign a consent form to confirm their willingness to participate.
2. Saliva Sampling: Participants will provide saliva samples on a weekly basis. These samples will be collected using a specially designed Salurate system, which includes a swab, a test cartridge and a smartphone app. The app will capture an image of the test cartridge and transmit it to the study's central database.
3. Data Collection: Along with saliva samples, participants' clinical data will be collected and matched with their test results. This data will be encrypted and stored securely to ensure confidentiality.
4. Follow-Up: Participants will be monitored throughout their pregnancy to track any development of hypertensive disorders by their clinical team. There will be no additional

participant visits for the purpose of the study. At the conclusion of pregnancy, outcomes will be collected from the medical notes.

What are the possible benefits and risks of participating?
Benefits:
- There are no direct benefits to the participants taking part. Their participation may benefit women in future pregnancies, who may benefit from early detection of hypertensive disorders, allowing for timely intervention and management.
Risks:
- Inconvenience: The primary risk involves the inconvenience of providing saliva samples. If the swab-taking process causes discomfort or injury, participants are advised to pause and contact a member of the study team.

Where is the study run from?
The study is sponsored by Morgan Innovation and Technology Ltd., with the primary research being conducted at St. George's University Hospitals NHS Foundation Trust and Epsom and St. Helier University Hospitals NHS Trust. The study involves multiple sites to ensure a diverse participant pool and comprehensive data collection.

When is the study starting and how long is it expected to run for?
May 2023 to June 2026

Who is funding the study?
The study is funded by a grant from Innovate UK, a government agency that supports business-led innovation.

Who is the main contact?
Professor Baskaran Thilaganathan, basky@pobox.com

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
337290

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61551, Grant Code 10053908, IRAS 337290

Study information

Scientific Title
Validation of salivary uric monitoring for early prediction of hypertensive disorders of pregnancy

Acronym
The Salurate Study

Study objectives
To assess whether the incorporation of the Salurate pregnancy remote self-monitoring system into the care pathway of pregnant women can enable the early prediction of hypertensive disorders of pregnancy (HDP) before the onset of clinical symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/08/2024, East of England – Cambridge East (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8096; cambridgeeast.rec@hra.nhs.uk), ref: 24/EE/0123

Study design
Multi-center observational analytical cohort

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Salivary uric monitoring for early prediction of hypertensive disorders of pregnancy

Interventions
While waiting to have their first scan, potential participants will receive a copy of the Salurate study information leaflet. After the scan is done, potential participants will be assessed for an ASPRE risk (a HDP screening algorithm) to determine if women have a high, medium or low chance of developing HDP.
The clinical team will emphasize the voluntary nature of participation and the participant's freedom to withdraw from the study at any time without affecting their regular care. It will be made clear to potential participants that there are no direct benefits to participating in this study, as the results will not be accessible to their clinical team, and no additional clinical intervention related to the trial will be carried out.

After signing the consent form, the participant will be introduced to the sample kit. It will be made clear that the only procedure outside of standard antenatal practice is that once per week, at the same time and before drinking, eating, exercising, or teeth cleaning, the participant will take a saliva sample and apply it on a test paper (encapsulated in a test cartridge), which colour will change depending on the concentration of uric acid in women's saliva. Using the app developed for the trial, the Salurate app, they will be asked to take a picture of the test cartridge and upload it using the app. The picture will be sent to a secure server (cloud-based).

Data related to pregnancy outcomes will equally be collected after delivery for the research team to analyse the outcomes of this trial. The results of this study are expected to provide valuable insights into the potential of the Salurate pregnancy remote self-monitoring system to predict HDP onset and enable proactive management.

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Clinical diagnosis of hypertensive disorders of pregnancy, including gestational hypertension, pre-eclampsia and chronic hypertension with superimposed pre-eclampsia. Diagnoses will be in line with ISSHP definitions, and data will be collected at the conclusion of pregnancy.

Secondary outcome measures
Collected within 6 weeks of the conclusion of pregnancy:
1. Small for gestation age fetus or fetal growth restriction i.e. neonates whose birth weight is less than the 10th percentile for that particular gestational age or two standard deviations below the population norms on the growth charts. Fetal growth restrictions includes evidence of placental insufficiency e.g. abnormal antenatal fetal doppler measurements
2. Gestational diabetes, defined as any degree of glucose intolerance with onset or first recognition during pregnancy. Diagnosed by oral glucose tolerance test or home blood glucose monitoring
3. Sampling adherence, including frequency of missed samples, dropout rate and number of ‘dry’ samples received

Overall study start date

31/05/2023

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Women, 16 years old or over with a singleton pregnancy
2. Viable intrauterine pregnancy on the 10-14 week scan
3. High risk (≥1:100) of HDP as determined by the ASPRE [14] algorithm*
4. Medium risk of HDP as defined by an ASPRE risk between 1:100 and 1:300
5. Able to provide informed consent
6. Gestation at enrolment ≤16 weeks
*Risk assessment based on: maternal factors, Mean Arterial Pressure, Uterine Artery Pulsatility Index, maternal serum pregnancy-associated plasma protein – A and placental growth factors

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 4,000; UK Sample Size: 4,000

Key exclusion criteria
1. Any significant medical co-morbidities which may potentially interfere with participation in or achieving the objectives of the study
2. Presence or history of severe mental illness that means the participant is unable to use Salurate independently
3. Any significant learning disability that means the participant is unable to use Salurate independently
4. Educational status or language barrier that influences capacity to use the App or understand the IFUs
5. Women who are physically incapacitated such as to make manipulation of the sampling system uncomfortable or impractical, as judged by the recruiter
6. Women who do not have access to a smartphone and/or internet data at home
7. Women who have been diagnosed with severe gingivitis or periodontal disease
8. Women who have been diagnosed with oral cancer

Contraindications
1. The potential participant suffers from severe nausea and vomiting in pregnancy.
2. The potential participant has infected, inflamed, cut/scraped or painful areas in their mouth.

Date of first enrolment
11/09/2024

Date of final enrolment
28/11/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St George's Hospital (tooting)
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
St Helier Hospital
Wrythe Lane
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Sponsor information

Organisation
Morgan Innovation and Technology (United Kingdom)

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Sponsor type
Industry

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ROR
https://ror.org/01vspgn73

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study intend to be published in a publicly available repository once all future studies related to the Salurate device are completed and data has been published. Prior to this anonymised data is available on request by contacting the chief investigator directly, and appropriate datasets will be provided to interested parties.

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 5	24/07/2024	24/09/2024	No	Yes
Protocol file	version 4	04/07/2024	24/09/2024	No	No
Protocol article		18/04/2025	25/06/2025	Yes	No