SALURATE

Participant Information Sheet

RESEARCH STUDY

Saliva self-testing for early detection of blood pressure problems in pregnancy

LED BY

NHS
St George's University Hospitals
NHS Foundation Trust

NHS
Epsom and St Helier
University Hospitals
NHS Trust

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morgan
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Study short title: The Salurate Trial

Research team: Professor Basky Thilaganathan (Chief Investigator), Doctor Ramesh Ganapathy (Principal Investigator), Doctor Basia Chmielewska (Research Fellow)

Sponsor: Morgan Innovation & Technology Ltd**.**

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Invitation to participate in the Salurate Study:
We, Morgan Innovation & Technology Ltd., the sponsor of the Salurate Study, would like to invite you to participate in our research study. The decision to join is entirely yours, and we want to ensure that you have a clear understanding of the purpose of the study and what would happen if you take part of the study. Your midwife and the research team will be available to guide you through the information and address any queries you may have.
Take the time to thoroughly review the information provided. Feel free to reach out if you have any questions or concerns.

Part 1 of this information sheet outlines the purpose of the study and what will happen if you take part

Part 2 details how the study will be conducted and how your data will be managed.

Part 1

1. What is the purpose of the study?

The Salurate Study explores a possible connection between the level of uric acid (a chemical) in saliva and the likelihood of developing blood pressure problems during pregnancy, also called Hypertensive disorders of pregnancy (HDP).

2. What is Salurate?

Salurate is a home-use, self-sampling medical device intended to predict blood pressure problems in pregnancy. Salurate monitors the concentration of Uric Acid in pregnant women's saliva over a period of several weeks to generate a prediction of a hypertensive event before symptoms occur.

A smartphone app is used in conjunction with the Salurate kit to instruct users and submit images of the test to a secure cloud-based server. To measure the amount of Uric Acid in saliva, it is necessary to collect saliva from under the tongue first thing in the morning using the sterile foam swab provided and apply this sample to the colorimetric test paper (enclosed in a test cartridge). Uric acid in saliva reacts to produce a change in test paper colour (purple colour of varying intensities), which is proportional to uric acid concentration. Users must photograph the test cartridge using the Salurate app on their smartphone, and this image is automatically sent to the server. To generate an accurate prediction, the user must take weekly saliva samples until the end of their pregnancy.

3. What is already known?

Salivary uric acid has been identified by some researchers as having the potential to predict HDP, but there are differing opinions. Further focused studies are required to conclusively establish the correlation between salivary uric acid levels and healthy versus high-risk pregnancies.

4. Why are you doing this research?

Hypertensive disorders of pregnancy are serious medical conditions that affect approximately 10% of pregnancies worldwide. These conditions affect women during pregnancy and after childbirth and can also affect the health of the baby. If the research study demonstrates Salurate's predictive capabilities are reliable and accurate, its implementation could lead to improved maternal and fetal health outcomes. Early detection before symptoms appear may enable doctors and midwives to initiate appropriate interventions promptly, reducing the incidence and severity of HDP.

5. What would taking part involve?

If you choose to take part, you will be given a test kit to take home. Once a week, you take a sample of your saliva first thing in the morning, using our sampling kit and apply this to our test cartridge. You then take a photo of the test cartridge using a free smartphone app. The Salurate App is a custom-designed smartphone app that you will need to install on your smartphone. You can download it for free on iOS and Android.
The Salurate app accesses your camera and knows the make and model of your phone. The app will occasionally send notifications. This is required for the app to function correctly. The app will not access your phone gallery or other files. The app will need an internet connection to send the images of the test cartridge to the server. If you are not using a Wi-Fi connection, the app will use your mobile data allowance, and if any extra costs occur due to the usage, you will not be reimbursed.
This quick, painless test takes about five minutes and is done once a week until your baby is born.

6. Can I interpret my test results?

No, you will not be able to interpret your results from the colour changing in the test cartridge. It is not possible to correctly interpret results by eye. Uric acid levels fluctuate naturally in the body, so it is normal to have a range of results. The prediction algorithm uses advanced techniques over several weeks before it makes a prediction.

7. How many participants are you planning to involve in the study?

We are planning to have 4000 pregnant women participating in the Salurate Study.

8. What alternatives are available to potential participants?

The Salurate Study will not influence or change your usual care. Please be aware that Salurate does not replace your routine prenatal visits.

9. What are the possible benefits of taking part?

Although there are no direct benefits for you, in the future the Salurate test may be able to identify high-risk pregnancies before symptoms appear. This would give doctors and midwives the opportunity to offer additional care to improve the outcomes of pregnancy.

10. What are the possible disadvantages and risks of taking part?

Aside from 5 minutes of your time per week, there are no anticipated disadvantages. You may feel slight discomfort when obtaining a sample of saliva from under the tongue.

11. What to expect during the recruiting and consent process?

When you visit the Clinic for your first scan, one member of the research team will go through this information sheet with you. They will show you how to take a sample, use the app, give you a supply of kits, and answer any questions you may have. If you agree to participate, they will ask you to sign a consent form. Copies of this information sheet and the consent form are yours to take away.

You might have to provide a saliva sample on recruitment day so the healthcare professional can set up your account in the Salurate app. By doing this, the healthcare professional can show you how to do the test and upload a picture of the test device.

12. What will happen if I don't want to carry on with the study?

Taking part in the study is completely voluntary; whether or not you participate will have no influence on the clinical care you will receive. You may begin the study and decide to stop at any time without giving a reason, and giving up will have no effect on you or your baby's care.
If you have any questions, now or later, about the study or would like to withdraw, please ask to speak to your midwife or speak/ email Dr Basia Chmielewska (barbara.chmielewska00@stgeorges.nhs.uk).

13. What if there is a problem?

Any complaint about the way you have been dealt with or any possible harm you might suffer will be addressed. Please inform your midwife or send an email to Dr Basia Chmielewska - barbara.chmielewska00@stgeorges.nhs.uk

14. What if something goes wrong?

If you have any concerns or want to complain about any part of your involvement in this study, you can talk to the researchers. If you are not happy with the study and want to make a complaint, you can use the NHS complaints process – your hospital will tell you how. You can also talk to the independent Patient Advice and Liaison Service (PALS) at your hospital.
If something goes wrong and you are harmed during the research, and this is due to someone's negligence, you may have grounds for legal action for compensation against the study sponsor (Morgan Innovation & Technology Ltd.), but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

Part 2

15. What will you know about me?

The trial research team will need to use information from your medical records for this research study. This information will include your initials, NHS number, full name, and contact details provided by the trial sites for the research.

Your Study ID is the only identifier linked to your results. After your baby is born, your results will be compared to specific details related to your pregnancy. Once the study is complete, the study findings will be available on the Salurate website and published for the medical community. Your identity and collected data will remain anonymous and confidential apart from the Study ID (code number). All the information collected from you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018.

16. How will you use information about me?

Your weekly test results will be matched with specific data from your medical records. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

17. How will my information be kept confidential? Will it be in accordance with the General Data Protection Regulation (GDPR)?

Your information will be anonymised and stored securely by the study sponsor and the study data controller, Morgan Innovation & Technology Ltd, and by the St. George's clinical research archive, for a minimum of 15 years. Where it is relevant to your participation in this clinical trial, data collected during this study and sections of your medical records and

those of your baby (both paper and electronic) may be looked at by individuals from the clinical research team, regulatory authorities or from the NHS Trust. The information held by the NHS may be used to keep in touch with you and to follow up on your status for the purposes of the study. You may be contacted during the trial if there are any issues with sample taking. The information collected about you may be used to support related research in the future and may be shared anonymously with other researchers.
All the information collected from you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018.

18. What will happen to the results of this study?
Once the study is finished, you can make a request to see the results through your obstetrician or midwife. Results of the study will be published in peer-reviewed journals and presented at national and international conferences.

19. Who is organising and funding this study?
The Salurate Study is being organised by Morgan Innovation & technology Ltd (sponsor), St George's Hospital NHS Foundation Trust and Epsom and St Helier University Hospitals NHS Trust (trial sites). The study was funded by Innovate UK, a non-departmental public body operating at arm's length from the Government as part of the United Kingdom Research and Innovation Organisation. Innovate UK provides money and support to organisations to develop new products and services.

20. How have patients and the public been involved in this study?
The clinical trial sponsor and the research team generated draft documentation for participants and the Salurate app, which were presented to the charity Action on Pre-eclampsia [APEC]. Through them, a Patient and Public Involvement Group reviewed all documents and the app, providing the sponsor with relevant feedback which was implemented.

APEC is a charity dedicated to raising public awareness and improving the care of people impacted by pre-eclampsia, a hypertensive disorder of pregnancy. APEC have an extensive network of former and current patients, as well as healthcare professionals.

21. Who has reviewed this study?

All research studies in England involving people are reviewed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and by an independent group of people known as The Research Ethics Committee (REC). Both entities provided a favourable opinion regarding the study.

22. What if relevant new information becomes available?

In certain situations, we discover new information about the device. If any new relevant information is available, a doctor or a member of the research team will make sure to promptly inform you and have a discussion about whether it's best for you to continue in the study.

23. Will my GP be informed regarding my participation?

With your consent, your GP will be informed of your participation in the trial; this contact will be for information purposes only.

24. What will happen to the samples I give?

Once you have completed the test and uploaded a picture of the sample, you can throw away the test cartridge and the used swab in your normal household waste.

25. What are my choices about how my information is used?

You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us, and we will stop. We need to manage your records in specific ways for the research to be reliable. This means

that we won't be able to let you see or change the data we hold about you.

26. Who can I contact if I have a complaint regarding how my data was handled?

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

More information on how health researchers use information from patients can be found at:

- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

27. Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/
- by asking one of the research team members, Dr Basia or your midwife.
- by sending an email to Dr Basia - barbara.chmielewska00@stgeorges.nhs.uk
- by ringing us on 020 8725 0071.

Disclaimers:

1. If you are living with a learning disability or a severe mental illness, to participate in the trial you must be able to use a smartphone and handle the Salurate kit independently.

2. If you are experiencing severe painful inflammation in your gums (gingivitis), this may impact your participation in the study as taking a sample may be painful, or affect the results. This does not need to be diagnosed by a dentist and will be discussed with you at recruitment.

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Thank you for taking the time to read this leaflet. We appreciate the support of all participants. Your participation will help us in our efforts to continually improve the care of pregnant women in the future.