IRAS ID: 307873

PARTICIPANT INFORMATION SHEET

MAGIC (Maternal GBS Identification) study

Full title: Molecular detection of Group B Streptococcus (GBS, Streptococcus agalactiae) in pregnant women: study of a novel diagnostic test.

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1: Purpose of this study and what will happen

Q 1. What is the purpose of the study?
A. We aim to trial a new diagnostic test which can rapidly detect Group B Streptococcus (GBS). GBS is a bug which is present in the bodies of 1 in 5 pregnant women and, if transmitted to the baby during birth, can cause a dangerous illness. To trial this new diagnostic test, we hope to obtain information about pregnant women, their pregnancies, deliveries and babies, and swab samples from the vagina to test for GBS.

Q 2. Why have I been invited?
A. You have been invited to participate in this study because you are attending the Rosie Hospital for antenatal care during your pregnancy and the care you will receive today routinely includes obtaining a swab from the vagina. This is an opportunity to take an additional swab to evaluate the new test for GBS.
We plan to include 200 women receiving antenatal care at the Rosie Hospital.

Q 3. Do I have to take part?
A. No, you do not have to take part. It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

Q 4. How will I be asked to participate?
A. After you have arrived at the clinic, the midwives or doctor initially meeting you for your clinical care will know whether you are eligible for the study. With your permission, that midwife

or doctor will invite you to talk to one of the research team who should be available while you wait in clinic. This member of the research team will go through this information with you, answer any questions you may have, and confirm with you whether you would like to take part in the study.

Q 5. What will happen to me if I take part?

A. If you agree to participate in the study, you will sign the Consent Form and be given a copy of this to take away and refer to later.

Participation in the study will allow the research team to collect the information and samples which are required to trial the new diagnostic test for GBS. This process will only require this one meeting with you today; all other information gathered from your medical notes will be done by the research team remotely and usually you won't be contacted again.

Specifically, participation in the study involves the following:

1. The research team member will work with the clinical team in the clinic to perform the care you need, with the additional research swab tests for GBS taken at the same time as your routine vaginal examination (in order to minimise the additional burden of the study as much as possible). There will be four vaginal swab samples taken all at the same time (one for the clinical requirement and three research samples). Obtaining the research swabs will only require a few seconds.
2. Your clinical records will be accessed to obtain information on the outcome of your pregnancy (such as the baby's birth weight, whether you had complications, for example, infection). Your baby's clinical notes will also be accessed to determine what special care (if any) your baby required after birth.

Q 6. What do I have to do?

A. To take part, you simply need to sign the consent form and have the additional swab tests taken from the vagina during the examination that will be conducted anyway as part of your care.

Q 7. What are the possible disadvantages and risks of taking part?

A. There are no risks to you. Obtaining the extra swab test samples may be slightly uncomfortable.

Q 8. What are the possible benefits of taking part?

A. Your participation in this study will hopefully help develop a better test for GBS that could benefit pregnant women in the future. It will not benefit you directly as you will be having the standard method of assessment for GBS and this result will be used to guide your care.

Q 9. What happens when the research study stops?

A. We plan to store your information and the samples we obtain for 5 years. If future developments in pregnancy care suggest that your data might be useful in other studies we could run, we may use your data in a new study. However, we will store the data only for as long as needed and destroy the data earlier if it is thought to be no longer useful.

Q 10. What if there is a problem?
A. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Part 2: Study conduct

Q 11. What will happen if I don't want to carry on with the study?
A. You can stop being part of the study at any time, without giving a reason. You can also request that we destroy all samples and information that we have collected and not to access your medical records. But, unless you specifically request this, we may use the information and samples collected up to that point and access your medical records. If you decide you do not wish to continue, please email us at paoandghod@medschl.cam.ac.uk or call us on +44 (0)1223 336871. Your routine clinical care will not be affected in any way.

Q 12. What if there is a problem?
A. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (please email us at paoandghod@medschl.cam.ac.uk or call us on +44 (0)1223 336871). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The office dealing with complaints is the Patient Advice and Liaison Service (PALS). You can call them on 01223 216756 or email them at pals@addenbrookes.nhs.uk. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Q 13. Will my taking part in the study be kept confidential, and my information protected?
A. Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will use information from you, your medical records and from the research visits. We will only use information that we need for the research study. The only people who will know your identity are doctors working in the Rosie Hospital who are involved with the research and they are bound by strict laws of confidentiality. Anyone else involved in the study will use an anonymous identifying number and they will be unaware of your identity. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data for future research. We will make sure no-one can work out who you are from the reports we write.

Cambridge University Hospitals NHS Foundation Trust (CUH) and The University of Cambridge are the Sponsors for this study based at the Rosie Hospital, Cambridge. They will be using information from you and your medical records in order to undertake this study and will act as

the data controller for this study. This means that they are responsible for looking after your information and using it properly. The Sponsor organisations will keep identifiable information about you for 5 years to ensure your safety and allow the study to be reviewed by the authorities after it is finished.

Your rights to access, change or move your information are limited, as the Sponsor organisations need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsors use your information using the information below:
- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk
- For University of Cambridge, please visit: https://www.medschl.cam.ac.uk/research/information-governance/, or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

Q 14. How will the research team collect, store, and use my information?
A. Cambridge University Hospitals will collect your name date of birth, hospital number, NHS number and contact details. We collect this information in case we need to contact you about this study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.
Individuals from the Sponsors and regulatory organisations may look at your medical and research records to check the accuracy of this study. Cambridge University Hospitals will pass these details to the Sponsors along with the information collected from you, your swab test results, and your medical records. The only people in the Sponsor organisation(s) who will have access to information that identifies you will be people who need to contact you in relation to this study and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about you from this study for 5 years after the study has finished.

We will use information from you, your swab test results, and your medical records for the research study. All information collected about you as a result of your participation in the study will be kept strictly confidential. Your personal and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed to participate in this study you will be allocated a Participant Identification Number. This is a unique number which will be used on all your study documentation. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details. Only anonymous study data, without any personal information will be published at the end of the study.

We will keep all information about you safe and secure. The security of storage will fulfil all regulatory requirements for the control of personal information. Electronic documents will be stored in password-protected computers and files, and paper documents (including your signed consent form) will be stored in a locked office, where access fulfils the UK regulatory requirements for the storage of personally identifiable and sensitive data. We will not send any of your personally identifiable data outside the UK or to any commercial entities.

Q 15. Can I request that my information is erased?

A. We are planning to retain the information we collect for 5 years, but we will store the data only for as long as needed and destroy the data earlier if it is thought to be no longer useful. However, you can stop being part of the study at any time, without giving a reason. Following the initial meeting with the research team, if you would like us to stop collecting information about your health and the outcome for your baby please contact us and we will stop. You can also contact us at any point and request that we securely destroy all the information and samples we have collected from you.

Q 16. Where can I find out more about how my information is used?

A. You can find out more about how we use your information by asking one of the research team: please email us at paoandghod@medschl.cam.ac.uk or call us on +44 (0)1223 336871. If you have any concerns about the use of your personal data you can contact the hospital's Data Protection Officer, Cambridge University Hospitals NHS Foundation Trust, Box 153, Hills Road, Cambridge, CB2 0QQ, or by email to gdpr.enquiries@addenbrookes.nhs.uk. The research is co-sponsored by Cambridge University and you can contact the Cambridge University Data Protection Officer at the Information Compliance Office, University of Cambridge, The Old Schools, Trinity Lane, Cambridge, CB2 1TN, telephone: 01223 764142 and email data.protection@admin.cam.ac.uk.

Q 17. Will my GP be involved or informed?

A. Your GP will not be required to contribute to the study. However, with your permission, we will write to your GP and let them know you are participating in the study and what is involved.

Q 18. What will happen to the samples I give?

A. We plan to obtain four vaginal swab samples (one for the clinical requirement and three research samples) from you in the clinic at the same time as your routine vaginal examination. The samples will be stored securely for 5 years but we will store the data only for as long as needed and destroy the data earlier if it is thought to be no longer useful. The samples will be stored in locked freezers in Cambridge University laboratories which are in turn kept in a secure locked area, and will be disposed of at the end of the research period in accordance with the UK Human Tissue Authority code of practice.

We will analyse the different samples in order to compare the accuracy of the different tests we have for the GBS bug. At this stage we want to compare four different tests, however new tests

might be developed in the future which we may also want to trial using your samples. We will not use any human cells or tissue in the sample for research.
It is possible that we might identify a novel test for GBS which has commercial value. The expression used in this situation is that you give your samples as a "gift". i.e. that by consenting to the study, you allow us to analyse the samples in any way we wish in the future with the aim of better detecting GBS or understanding pregnancy complications and outcomes.
Samples and data may be sent to external collaborators for processing. Any samples passed on will only be used for purposes relating to this research. Any transfer of data or samples will be transferred under a formal security and confidentiality agreement signed by both parties. All your personal information will have been removed and the other researchers will be unable to identify you. We will only pass on samples which are identified by a code number and we will not pass on information that allows external collaborators to identify you. You will not profit from any future study or collaboration that uses your sample.

Q 19. Will I be able to request that my samples are destroyed?
A. Yes. If you decide that you no longer wish to take part in the study, we will ask you whether you want us to destroy all the samples we have collected. If you opt to have your samples destroyed we will do this.
If you do not request us to destroy the samples we may still use them as described in this leaflet until the end of the research period, at which time the research team will dispose of the samples in accordance with the UK Human Tissue Authority code of practice.

Q 20. Will any genetic tests be performed?
A. The only genetic analysis that will be performed will study the bacteria present on the swab. We will not analyse your DNA.

Q 21. Will you report any result that allows identification of the baby's paternity?
A. No.

Q 22. What will happen to the results of the research study?
A. The results of the study will be anonymous and you will not be able to be identified from any of the data produced. When the results of this study are available they may be published in peer reviewed medical journals and used for medical presentations and conferences.
Anonymous datasets from the study may also be made available to other researchers in line with national and international data transparency initiatives.
We will place details of our findings on the Department of Obstetrics & Gynaecology web site: https://www.obgyn.cam.ac.uk. However, no-one will be able to identify you as one of the participants in the study.

Q 23. Who is organising and funding the research?
A. The study is funded by the Addenbrooke's Charitable Trust and research in the department is also supported by the National Institute of Health and Care Research, the Research and Development arm of the NHS.

Q 24. Who has reviewed the study?

A. The scientific case for performing the study was assessed by the Addenbrooke's Charitable Trust and the study was peer reviewed. The ethics of the study was assessed by an independent group of people, the Bromley Research Ethics Committee. Their role is to protect your safety, rights, wellbeing and dignity. Both the scientific case and ethics of the study have been reviewed and given favourable opinion.

Q 25. Contact for Further Information

A. Prof GCS Smith. The research going on in the Department of Obstetrics & Gynaecology is described on the web site (http://www.obgyn.cam.ac.uk/) and, ultimately, the results of this study will be posted there as well. If you have any specific queries, you can also email us at paoandghod@medschl.cam.ac.uk or call us on +44 (0)1223 336871.