Routine testing for Group B Streptococcus (GBS3)

Participant Information Sheet- Rapid test

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IRAS Project ID: 263682

Our research trial

- It is important you understand why the research is being done and what it will involve for you.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.
- Ask us if there is anything that is not clear or if you would like more information.

1. What is the purpose of the trial?

This trial is looking at whether testing pregnant women to see if they carry group B Streptococcus (GBS) reduces the risk of infection in newborn babies compared to the current strategy in place in the UK. The current strategy in the UK is to offer antibiotics during labour to women who are considered at risk of their baby developing GBS infection (Risk Factor Based Strategy).

There are two different tests, which we are comparing against the current strategy:

- A test at an antenatal appointment approximately 3-5 weeks before expected pregnancy due date (Enriched Culture Medium Testing)
- Bedside test at start of labour (Intrapartum Rapid Testing)

2. What is Group B Streptococcus?

Group B Streptococcus is also known as GBS, Strep B or group B Strep. It is a common type of bacteria that normally causes no harm. In the UK, 1 in 4 pregnant women carry GBS in their vagina and (back passage) rectum. You're unlikely to know you carry it.

If you carry GBS, your baby will be exposed to it around labour and birth. While most babies won't be affected, there is a very small chance of your baby becoming seriously ill or even dying. In extremely rare cases GBS infection can also cause miscarriage, early labour or stillbirth.

All hospitals taking part have been randomly allocated to either undertake testing pregnant women for GBS carriage or continue following current UK GBS strategy. This means all women who are pregnant and give birth at this hospital will be tested for GBS and treated in the same manner (unless advised otherwise by your doctor or midwife).

Your hospital has been randomly allocated to undertake testing pregnant women for GBS carriage and has been allocated to the bedside test at start of labour.

3. What would taking part involve?

The test needs a swab taken from both your vagina and rectum (back passage) when you are in labour. This swab is taken by a healthcare professional. The procedure will not hurt but it may be slightly uncomfortable. The swab will be immediately put into a machine by a member of your care team and the results will be available within one hour. If the result is positive for GBS, you will be offered antibiotics immediately. (If you are planning to give birth at home or in a midwife only led unit you may be offered the option of a rapid test antenatally in hospital after the 35th week of your pregnancy.)

The trial will use information that is already routinely collected by the NHS about your labour and birth and your baby's health. We will also aim to use other routinely collected information about any childhood illnesses, to see if there is any connection with events at birth, including antibiotic use. We will link all of this information together in a secure database called a "Trusted Research Environment" managed by the Health Informatics Centre located at the University of Dundee using yours and your baby's NHS numbers, postcode and dates of birth. . A Trusted Research Environment (TRE) is a secure space for researchers

to access sensitive data. Once the information has been linked together, the information will be anonymised and any identifiable information will not be looked at. All the anonymised routinely collected information will be permanently deleted from the secure database once the findings have been published.

In addition, 100 women at your hospital will have a small amount of non-sensitive information collected which is not routinely recorded in the NHS databases. If you are part of this group, you will be assigned a trial identity code and your NHS number, date of birth and postcode will be entered into the trial database. This will ensure your information is linked with the routine data collected.

Under UK Data Protection laws the University of Nottingham is the Data Controller (legally responsible for the data security) and the Chief Investigator of this trial is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and 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 we use your information and read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx. You can also read the GBS3 trial specific privacy notice at: https://www.gbs3trial.ac.uk/documents/gbs3-participant-privacy-notice-final2.0-21jan2022.pdf

The data collected for the trial will be looked at and stored by authorised persons from the University of Nottingham (who are organising the research) and the University of Dundee (who store the data). They may also be looked at by authorised people from regulatory organisations to check that the trial is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All research data will be kept securely after the end of trial for 7 years at the University of Nottingham. After this time the data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team who have been given permission by the data custodian will have access to your personal data and any identifiable personal data will be deleted by the end of the trial.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Only anonymous data will be shared in this way.

4. What will happen if I don't want to take part in the trial?

If you do not want your data (or your baby's data) to be used for this trial, you have the right to opt out using the national data opt-out service. This is a service that allows you to opt out of all your health information being used for all future research and planning, (not just for this trial). For more information go to the "Your NHS data matters" website or speak to your GP.

If you opt out of your data being used after it has been collected and processed, unfortunately it cannot be erased, as it will have already been anonymised. If you do not want a swab taken you are free to decline, without giving any reason, and your treatment will not be affected in any way. Your routine data will still be used for trial purposes.

5. Who is organising and funding this trial?

This trial is funded by the NIHR Health Technology Assessment (HTA) Programme and sponsored by

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NOTTINGHAM CLINICAL TRIALS UNIT

GBS3 ROUTINE TESTING FOR GROUP B STREP

the University of Nottingham. The trial is managed by the Nottingham Clinical Trials Unit.

6. How to contact us

Principal Investigators Name:
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Thank you for reading this leaflet, you may keep a copy of this Participant Information Sheet if you wish. If you would like any further information, please visit www.GBS3trial.ac.uk