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Maternal Group B Streptococcus identification study

Submission date
13/10/2022

Recruitment status
No longer recruiting

Registration date
02/11/2022

Overall study status
Ongoing

Last Edited
10/01/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Pregnant people who are 16 years old and over who attend the Rosie Hospital for antenatal care during their pregnancy and the care they will receive routinely includes obtaining a swab from the vagina

What does the study involve?
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 one meeting with the participants; all other information gathered from the medical notes will be done by the research team remotely and usually the participant 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 needed, with the additional research swab tests for GBS taken at the same time as the 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. The participant's clinical records will be accessed to obtain information on the outcome of the pregnancy (such as the baby's birth weight, whether there were any complications, for example, infection). The baby's clinical notes will also be accessed to determine what special care (if any) the baby required after birth.

What are the possible benefits and risks of participating?
The benefits are that 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 the participant directly as they will be having the standard method of assessment for GBS and this result will be used to guide their care. There are no risks to participants. Obtaining the extra swab test samples may be slightly uncomfortable.

Where is the study run from?
Rosie Hospital, Cambridge (UK)

When is the study starting and how long is it expected to run for?
November 2021 to October 2027

Who is funding the study?
Addenbrooke's Charitable Trust (UK)

Who is the main contact?
Prof Gordon Smith
paoandghod@medschl.cam.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
307873

Protocol serial number
Funder (Addenbrooke's Charitable Trust) reference number 900336

Study information

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

Acronym
MAGIC

Study objectives
Primary research question: Do we have a diagnostic test that is better able to detect Group B Streptococcus (GBS) from high vaginal swabs in pregnant women than the current NHS standard of care?
Secondary research question: Is the presence of GBS detected by existing or novel methods associated with poor neonatal outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/08/2022 by the Proportionate Review sub-committee of the London - Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK, +44 (0)207 104 8118; bromley.rec@hra.nhs.uk), ref: 22/PR/1045

Primary study design
Observational

Study design
Single-centre observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Group B Streptococcus agalactiae in pregnant women

Interventions
Women will be recruited from clinical areas which often require speculum examinations and swabs taken as part of the routine assessment in the Rosie Hospital, Cambridge (e.g. the Maternity Assessment Unit and the Preterm Birth Prevention Clinic). 200 women will be recruited, in accordance with the sample size calculation.

Four swabs will be obtained from each participant, one swab for the clinical requirement and three research swabs for:
1. Enriched culture, specific for Group B Streptococcus (GBS) (gold standard)
2. DNA extraction for multiplex PCR (sip qPCR, 16S rRNA PCR-PCR, and a human DNA control, RNASEH) and sequencing
3. Optimised DNA extraction for Nanopore sequencing (for future testing)

All DNA extraction and analysis will be of non-human (i.e. bacterial) DNA. Data on maternal characteristics and maternal and neonatal outcomes will be collected from the electronic medical record.

Intervention Type
Other

Primary outcome(s)
Presence of Group B Streptococcus (GBS) in the maternal genital tract (positive/ negative) at the time of a clinically-indicated vaginal swab at any point in pregnancy, measured with the following methodologies:
1. Routine microbiological culture and sensitivity without enriched media
2. Enriched microbiological culture specific for GBS
3. DNA extraction for multiplex PCR, with two approaches:
3.1. qPCR for sip, a GBS-specific gene of which GBS has only one copy
3.2. Nested PCR-qPCR for a GBS-specific sequence of the 16S RNA gene, of which the genome has seven copies

Key secondary outcome(s)
Maternal and neonatal outcomes measured by examination of electronic medical records at the time of hospital discharge following delivery:
1. Mode of delivery
2. Complications with labour/delivery (e.g. fever, chorioamnionitis, intensive care admission)
3. Gestation at delivery (days)
4. Birthweight (kg)
5. Admission to the NICU (and indication for admission)
6. Stillbirth/neonatal death

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. Attending the Rosie Hospital, Cambridge, pregnant at any gestation, for an assessment which includes a vaginal examination and swabs taken
2. Aged 16 years old and over, and have the capacity to provide informed consent for themselves

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Sex
Female

Total final enrolment
250

Key exclusion criteria
Not meeting the inclusion criteria

Date of first enrolment
01/02/2023

Date of final enrolment
31/07/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Rosie Hospital
Robinson Way
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data will be available in relation to the studies described above (i.e. demographic, clinical and laboratory). Data will be available for sharing during the 5 years of data storage. Requests should be sent to Prof GCS Smith (paoandghod@medschl.cam.ac.uk) and reasonable requests with an acceptable scientific case will be considered. Transfer of data will require a Data Transfer Agreement (DTA), with the signature of the requester and a legal representative of the institution. The DTA will specify all conditions of the agreement and the scope of the work and will be negotiated by the Research Operations Office of the University of Cambridge. Participant identifiers will not be included in the data sent and researchers will be required to provide a commitment to refrain from using the data to try and identify participants. All participants have provided their written informed consent for their data to be used in this way.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	23/08/2022	31/10/2022	No	Yes