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Point-of-care diagnostic test for neonatal infection

Submission date
07/08/2019

Recruitment status
Suspended

Registration date
09/08/2019

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Infections and Infestations

[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
Being born before 37 weeks of pregnancy, also known as premature birth, is the leading cause of death among babies. Around 60 000 babies are born early in the UK each year with 40% of cases being associated with an infection. Among these cases the most commonly isolated bacteria are Ureaplasma. Ureaplasma in the lungs of the premature babies has been associated with an increased risk of lung disease, damage to the gut and bleeding on the brain compared with babies born early but are not infected. Administration of the correct antibiotic has been shown to eradicate Ureaplasma from the lungs, but a specific type of antibiotic (azithromycin) is required to treat these babies, one which is not given as routine practice. It is therefore imperative to obtain a rapid diagnosis of Ureaplasma to administer the correct treatment, but current diagnostic methods are expensive and take many days to obtain a result. This study will look at the feasibility of a newly developed diagnostic device to detect Ureaplasma among premature neonates.

Who can participate?
This study will focus on babies which are born prematurely between 25 and 30 weeks gestational age and are being ventilated as a high percentage of this group have previously been shown to be positive for Ureaplasma.

What does the study involve?
As part of routine care, ventilator tubes are cleared of mucus which can build up over time. It is this waste material, which we will use to assess the feasibility of the new device to detect Ureaplasma. Samples will be collected over an 18 month period from babies admitted to the Neonatal Intensive Care Unit at Singleton Hospital, Swansea. Samples will be run on the new device and compared to the current accepted method at Cardiff Metropolitan University.

What are the possible benefits and risks of participating?
The information that we aim to obtain from this study will enable neonatal teams in the future to quickly assess if a preterm baby has Ureaplasma in their lungs and may therefore help with treating that baby. Your baby will not directly benefit from participating in the study, because the results of any tests will not be made available to the team as these results will be preliminary. There are no foreseeable risks associated with participating in this study.

Where is the study run from?
Singleton Hospital, Swansea, UK

When is the study starting and how long is it expected to run for?
October 2019 to March 2021

Who is funding the study?
This study is funded by the Sir Halley Stewart Trust.

Who is the main contact?
The main contact for this study is Dr Michael Beeton (mbeeton@cardiffmet.ac.uk)

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Development of a rapid and cost-effective Point-of-Care diagnostic test for the detection of Ureaplasma infection among premature neonates

Study objectives
The novel diagnostic test will be able to detect the presence of the bacteria Ureaplasma in lung secretions obtained from perterm babies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2019, London - Brighton & Sussex Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 020 797 22567; NRESCommittee.SECoast-BrightonandSussex@nhs.net), ref: 19/LO/1285

Study design
Single centre screening study

Primary study design
Other

Study type(s)
Screening

Health condition(s) or problem(s) studied
Bacterial infection in ventilated preterm neonates

Interventions
As part of routine care, ventilator tubes are cleared of mucus which can build up over time. It is this waste material, which we will use to assess the feasibility of the new device to detect Ureaplasma. Samples will be collected over an 18 month period from babies admitted to the Neonatal Intensive Care Unit at Singleton Hospital, Swansea. Samples will be run on the new device and compared to the current accepted method at Cardiff Metropolitan University.

Intervention Type
Other

Primary outcome(s)

1. Sensitivity of the new diagnostic device - estimates of the new diagnostic device positive rate in comparison with qPCR methods currently used.
2. Specificity of the new diagnostic device - estimates of the new diagnostic device negative rate in comparison with qPCR methods currently used.
3. Estimate of the positive predictive and negative predictive value of the new diagnostic device as other basic measures of diagnostic accuracy given their relationship to sensitivity and specificity through disease prevalence .

Key secondary outcome(s))
Relationship between qPCR copy numbers and the new diagnostic device values obtained using regression analysis

Completion date
30/09/2021

Eligibility

Key inclusion criteria
Babies born between 25 and 30 weeks gestational age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Parents of any baby which are deemed not to have the capacity to consent
2. Parents of any baby who cannot speak English or Welsh
3. Baby receiving palliative care
4. Parents are under the age of 16 years
5. Baby under a care order
6. Any other reason that the clinical lead feels it may be inappropriate.

Date of first enrolment
01/10/2019

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Singleton Hospital
Swansea
United Kingdom
SA2 8QA

Sponsor information

Organisation
Cardiff Metropolitan University

ROR
https://ror.org/00bqvf857

Funder(s)

Funder type
Charity

Funder Name
Sir Halley Stewart Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes