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Quick bedside tests in newborns

Submission date
11/12/2024

Recruitment status
Recruiting

Registration date
15/01/2025

Overall study status
Ongoing

Last Edited
15/01/2025

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
We wish to explore targeted testing in neonatal intensive care to help decision-making around the best management of an unwell baby. The tests we explore will be currently or potentially deliverable using point of care tests (POCT) – these give rapid answers to clinical teams.

Who can participate?
Babies admitted to the neonatal unit being investigated or managed for possible infection or bowel problems.

What does the study involve?
We will use targeted sampling of blood, urine, stool or saliva over the first hours and days after a baby becomes unwell to see how different tests might help teams when management decisions are being made. These include decisions around antibiotic duration, pausing or restarting milk feeds, and types and amounts of fluids and intravenous feeds being given. We have chosen POCT based on what is already known about sick babies but are not yet used as part of normal care. The POCT results will not be shared with the clinical team and will not change care delivered. We will explore whether they perform well enough to help guide management decisions like stopping or re-starting feeds, stopping, reducing or re-starting intravenous nutrition, duration of antibiotics etc. We will also examine illness scores and how they correlate with POCT. We will also explore how clinical teams currently make decisions and how they would 'value' additional POCT information. The study is being undertaken as a higher degree (MD) by a medical doctor. The findings will help inform the design of a future study where clinicians would be given the results in real time to guide decision-making.

What are the possible benefits and risks of participating?
There are no real benefits as the results will not be known to the clinical teams at this stage because we do not know if they will work well enough to help make decisions. The only risk is that the blood that is taken is extra to clinical need. This is clear to families in information and on consent sheets. We will take the smallest amount possible for the tests and will adhere to current guidance on volumes of blood that can be taken from small babies.

Where is the study run from?
Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
September 2024 to August 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Janet Berrington, janet.berrington1@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Janet Berrington

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
352977

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Neonatal Quick Assays (NeoQUACK): an observational study of neonates in intensive care units and the application of point-of-care tests to assist clinical decision making

Acronym
NeoQUACK

Study objectives
We wish to explore targeted testing in neonatal intensive care to help decision-making around the best management of an unwell baby. The tests we explore will be currently or potentially deliverable using point of care tests (POCT) – these give rapid answers to clinical teams. We will use targeted sampling of blood, urine, stool or saliva over the first hours and days after a baby becomes unwell to see how different tests might help teams when management decisions are being made. These include decisions around antibiotic duration, pausing or restarting milk feeds, and types and amounts of fluids and intravenous feeds being given. We have chosen POCT based on what is already known about sick babies but are not yet used as part of normal care. The POCT results will not be shared with the clinical team and will not change care delivered. We will explore whether they perform well enough to help guide management decisions like stopping or re-starting feeds, stopping, reducing or re-starting intravenous nutrition, duration of antibiotics etc. We will also examine illness scores and how they correlate with POCT. We will also explore how clinical teams currently make decisions and how they would 'value' additional POCT information. The study is being undertaken as a higher degree (MD) by a medical doctor. The findings will help inform the design of a future study where clinicians would be given the results in real time to guide decision making.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Study design
Observational cohort longitudinal single-centre study

Primary study design
Observational

Secondary study design
Includes some qualitative elements

Study setting(s)
Hospital

Study type(s)
Diagnostic, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participation information sheet

Health condition(s) or problem(s) studied
Infant admitted to the neonatal intensive care unit undergoing testing for suspected (or confirmed) infection, or bowel concerns

Interventions

No changes to clinical care. Point of care tests will be performed on saliva, stool, blood or urine, from beginning of screening episode to physiological and nutritional recovery, discharge from the neonatal unit, withdrawal or death whichever is sooner.

Intervention Type
Other

Primary outcome measure
For each assay: positive and negative predictive values for each diagnostic category and area under the curve analysis to identify the best cut-off values from the time of screening to full physiological recovery

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2024

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Infant admitted to the neonatal intensive care unit (from 22 weeks gestation to 6 months postnatal age)
2. Infant undergoing testing for suspected (or confirmed) infection, or bowel concerns
3. Written informed consent from parents

Participant type(s)
Patient

Age group
Neonate

Lower age limit
0 Days

Upper age limit
6 Months

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Parents unwilling to consent
2. Infants being screened at or shortly after birth for risk factors alone but who are clinically well

3. Infants known to have severe multi-system congenital abnormalities. Infants known to have congenital gastrointestinal abnormalities at admission will be excluded for the first 48 hours, but eligible after this if infection or new bowel concerns occur
4. Infants undergoing therapeutic hypothermia

Date of first enrolment
01/03/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle Neonatal Unit
Ward 35
Newcastle
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Royal Victoria Infirmary
Newcastle upon Tyne
England
United Kingdom
NE1 4LP
+44 (0)191 2824519
nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The researchers will publish in peer-reviewed journals

Intention to publish date
28/02/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study may be available on request from Prof. Janet Berrington (janet.berrington1@nhs.net)

IPD sharing plan summary
Available on request