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Application of a point-of-care testing full blood count analyser in neonatal (<2 months) clinical care

Submission date
03/07/2025

Recruitment status
No longer recruiting

Registration date
29/12/2025

Overall study status
Completed

Last Edited
29/12/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The pathology team at Harrogate Hospital (sponsor) have the opportunity to trial a full blood count (FBC) analyser (Pixcell) to gather data to determine whether this device could potentially be used clinically in neonates (<2 months of age). The HemoScreen device can offer faster results, require smaller, less invasive blood samples, and the test can be performed on the neonatal ward, close to where the clinical care is being delivered.

Who can participate?
All neonates (male and female) under 2 months of age and their parents.

What does the study involve?
The clinical team will only request and collect blood samples that are necessary for the child's medical care. No extra samples will be taken, and the only tests done will be for a full blood count (FBC) using the samples already collected. If an extra FBC is done as part of the research study, the results will be anonymised and included in the research report. These results will not be used to make medical decisions and will not appear in the child's medical records. When an FBC is needed for the child's care, a blood sample will be taken using a standard blood tube. A small amount of blood (1–2 drops) from the lid of the tube will be placed into a special device and analysed using the HemoScreen machine. The rest of the sample will be sent to the hospital lab for routine testing and to help guide treatment. The results from the HemoScreen will be compared with the lab results. A statistical analysis will be done to see if the HemoScreen is suitable for use with newborns. Each child will only have blood used for this research on up to two occasions during their hospital stay.

What are the possible benefits and risks of participating?
This is a unique opportunity to develop a method for use in neonatal medicine. It would reduce the number of blood samples rejected due to clots, reduce the time taken for the clinical team to obtain a FBC and reduce the amount of blood needed for this test.

There are no known risks that we are aware of. The blood sample required is extremely small and it will be drawn from the lid of the tube.

Where is the study run from?
The special care babies unit (SCBU)at Harrogate and District Hospital Trust (HDFT)

When is the study starting and how long is it expected to run?
April 2024 to December 2025

Who is funding the study?
The Healthcare Science Innovation Fellowship programme, UK.

Who is the main Contact?
Nicky Hollowood, POCT Cross Site Lead, Integrated Pathology Solutions (IPS) and Research Fellow, nicky.hollowood@nhs.net

Contact information

Type(s)
Scientific

Contact name
Ms Nicky Hollowood

Contact details
Harrogate Hospital
Harrogate
United Kingdom
HG2 7SX
+44 (0)1423555858
nicky.hollowood@nhs.net

Type(s)
Public, Principal investigator

Contact name
Dr Nuthar Jassam

Contact details
Harrogate Hospital
Harrogate
United Kingdom
HG2 7SX
+44 (0)1423 555647
nuthar.jassam@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334547

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Application of POCT FBC analyser in neonatal (<2 months) clinical care

Study objectives
To ascertain whether a novel POCT FBC analyser (Pixcell HemoScreen) device is suitable for a larger-scale CE marking research project to enable clinical use of the device in neonates< 2months of age.
To determine whether the device could offer a solution for the clinical issue of clotted samples from this population group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/07/2024, West Midlands-Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048357; edgbaston.rec@hra.nhs.uk), ref: 24/WM/0076

Study design
Cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neonates < 2 months' blood samples are sometimes clotted when they reach the laboratory for full blood count (FBC) analysis, leading to repeat sampling and delays in results.

Interventions
This study looks at the feasibility of using a point-of-care testing device (Hemoscreen) for full blood count (FBC) analysis. The device will be placed on the neonatal unit, and samples will be analysed before they have an opportunity to clot. Results will be given within 5 minutes on the ward where clinical care is taking place.

Participants will be neonatal patients < 2 months of age resident at the special care babies unit in Harrogate Hospital. The neonatal unit nurses will do recruitment verbally. A minimum of 15

patients are to be recruited to make a library of a minimum of 30 samples (max. 2 samples per single patient) as recommended by the Altman and Bland graphical method as described in The Lancet 1986. This sample size would give a 95% Confidence Interval (CI) of about +/- 0.34S, where S is the standard deviation of the difference of the two methods used in this study (HemoScreen and Sysmex XN1000).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pixcell Medical Hemoscreen, Sysmex XN1000

Primary outcome(s)
Full blood count collected and measured at the point-of-care using the Pixcell Medical Hemoscreen device versus the hospital laboratory using a Sysmex XN1000 analyser at one time point.

Key secondary outcome(s))
The percentage of samples that can be processed at the point-of-care on the Pixcell Haemoscreen, but are clotted by the time of receipt in the laboratory, measured using laboratory records at one timepoint

Completion date
01/12/2025

Eligibility

Key inclusion criteria
< 2 months of age. No more than 2 samples used per patient

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
0 months

Upper age limit
2 months

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients without consent and patients > 2 months of age

Date of first enrolment
01/11/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Harrogate District Hospital
Lancaster Park Road
Harrogate
England
HG2 7SX

Sponsor information

Organisation
Harrogate and District NHS Foundation Trust

ROR
https://ror.org/05y3c0716

Funder(s)

Funder type
Government

Funder Name
Healthcare Science Innovation Fellowship Programme

Results and Publications

Individual participant data (IPD) sharing plan

The data that will be shared is the comparison data and analyser performance against the laboratory Sysmex XN1000. These will be published in a scientific journal, shared with parents who asked for the information to be shared with them and available upon Freedom of Information (FOI) request to Harrogate and District NHS Foundation Trust (HDFT).

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3		04/07/2025	No	Yes
Participant information sheet	version 4	04/07/2024	04/07/2025	No	Yes
Protocol file	version 4		04/07/2025	No	No