ISRCTN14617667 https://doi.org/10.1186/ISRCTN14617667

Comparing how well Neutrocheck works in comparison to current blood tests in spotting infections in patients with low white blood cells

Submission date
14/07/2025

Recruitment status
Recruiting

Registration date
18/07/2025

Overall study status
Ongoing

Last Edited
16/04/2026

Condition category
Haematological Disorders

[ ] 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
The aim of the NeutroD study is to assess the accuracy of a device - Neutrocheck – within a hospital setting, on patients with neutropenia. Neutropenia is a common side effect of chemotherapy and is characterised by low levels of neutrophils, which are a type of white blood cell. This increases the likelihood of a patient further developing neutropenic sepsis, a life-threatening condition that causes approximately 800 deaths/year in England and Wales. Neutropenic sepsis is diagnosed via blood test which measures the levels of both neutrophils and a protein called Creactive protein (CRP). If the blood test shows low levels of neutrophils and high CRP, then a patient is at risk of getting neutropenic sepsis. The standard of care for such patients is to receive antibiotics intravenously. This means the antibiotics, medication used to fight off the infection, are administered directly into a vein in the arm whilst the patient awaits results (15min-2hrs) from the blood test. The Neutrocheck device will detect neutrophil and CRP levels using just a finger prick of blood. The patient will then review their results using a colour chart and app. If Neutrocheck is as accurate as hospital laboratory tests, this could lead to the possibility of patients doing the tests at home so they would come into the hospital only if it was necessary, and receive results much faster than current hospital result waiting times. This further ensures antibiotic treatment is only administered to patients who require it.

Who can participate?
Men and Women aged 18 years or over, at risk of neutropenia or neutropenic sepsis who fulfil all of the inclusion criteria and none of the exclusion criteria.

What does the study involve?After having a maximum of two venous blood samples taken from their arm, training on how to use the device and conduct the test will be provided. The training will consist of a video tutorial and access to the device manual. After familiarising themselves with the device, they will conduct the test under the guidance of a research clinician. The test consists of using a finger prick to extract a blood drop from the participants finger and transferring the blood drop onto the device. After a wait of 10 minutes, the results can be interpreted by comparing the two coloured lines that appear to an indicator chart. The participants will also be provided with a phone with an app on it, which will use the phones'

camera to interpret the coloured lines. The study research clinician will assist with this. The trial has been split into two phases, during the pilot phase venous bloods will be taken, equivalent to no more than 4 teaspoons. Thereafter during the main phase of the trial no more than 2 teaspoon of blood will be taken. The results will be read by the participant and recorded by the research clinician. The device and the contents kit are single use and will be taken away by the study research clinician for safe disposal. The participant will be asked to complete a usability questionnaire after they complete the test.

What are the possible benefits and risks of participating?
Risks: Discomfort at the time of the finger prick and for a few hours following. Sometimes the discomfort can last until the next day; bruising may occur at the site of the finger-prick; in an extremely rare circumstance, there may be excessive bleeding from the finger-prick site; the risk of infection happening is very low; some people feel uneasy at the sight of blood and this may lead them to feeling faint or having a fainting; some people develop a mild reaction at the site of the finger-prick, from the plaster.
Benefits: There will be no direct benefits to participants for taking part, however we hope the information we gain from the study will potentially help to assess the accuracy and reliability of the device. In the future, this will allow testing for neutropenic sepsis to be done at home in a simple and easy to use way without the need to attend hospital or receive unnecessary antibiotics.

Where is the study run from?
Cambridge Clinical Trials Unit

When is the study starting and how long is it expected to run for?
February 2022 to December 2026.

Who is funding the study?
Innovate UK and 52North

Who is the main contact?
Trial Coordinator (Glenn Harden), glenn.harden@nhs.net
Chief Investigator (Hugo Ford), hugoford@nhs.net

Contact information

Type(s)
Public, Scientific

Contact name
Mr Glenn Harden

Contact details
Cambridge University Hospitals NHS Trust
Cambridge Clinical Trials Unit- Cancer Theme
Addenbrooke's Hospital, S4, Box 279
Hills Road
Cambridge
United Kingdom

CB2 0QQ
+44 1223348091
glenn.harden@nhs.net

Type(s)
Principal investigator

Contact name
Dr Hugo Ford

Contact details
Cambridge University Hospitals, NHS Foundation Trust, Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 1223 348894 Ext: 348894
hugoford@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
331579

Central Portfolio Management System (CPMS)
61264

Grant Code
10042629

Study information

Scientific Title
Evaluation of the diagnostic performance of Neutrocheck® compared with standard-of-care neutrophil and CRP readings in patients at risk of neutropenic sepsis

Acronym
NeutroD

Study objectives
The aim of the NeutroD study is to assess the accuracy of a device - Neutrocheck – within a hospital setting, on patients with neutropenia. The Neutrocheck device will detect neutrophil and CRP levels using just a finger prick of blood. The patient will then review their results using a colour chart and app. If Neutrocheck is as accurate as hospital laboratory tests, this could lead to the possibility of patients doing the tests at home so they would come into the hospital only if it was necessary, and receive results much faster than current hospital result waiting times. This further ensures antibiotic treatment is only administered to patients who require it.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/11/2024, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 808; cambridgecentral.rec@hra.nhs.uk), ref: 24/EE/0195

Primary study design
Interventional

Study design
Interventional non-randomized

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neutropenic sepsis

Interventions
Neutrocheck is a single-use, portable device that accurately detects neutrophil and CRP levels using a blood finger-prick. The device uses lateral flow technology, with innovative housing enabling the measurement of a cell and solute. The device will be used by participants who will measure the line intensity using a visual score card and an automatic reader tool which is available via the companion Neutrocheck app.

The participant will watch a video tutorial on how to use the Neutrocheck device. Two research venous blood draws will then be taken. The participant will then use the Neutrocheck device. The participant will take a blood finger prick and insert the blood sample into the device. Once the results are available, the participant will interpret their result using the visual card and by using the companion app.
Participants will be asked to complete a questionnaire after using the Neutrocheck device.

Patients enrolled from the CAU will use the device once during their CAU visit only, unless they go on to being admitted into a ward, where they will follow the process below for ward patients.
Patients enrolled from wards will use the Neutrocheck device daily until they either withdraw from the study, or are discharged home from the hospital.
Patients enrolled from routine clinics will use the Neutrocheck device in their regular clinics, which must be 2 weeks apart, for a maximum period of 6 months.

There are no follow up or end of trial visits. The NeutroD study is a single visit only study, and the total duration of participant involvement is from informed consent to using the device and completing a questionnaire. No treatment is administered as part of the study.

Intervention Type
Other

Primary outcome(s)
C-reactive protein and Neutrophils are measured by inserting a drop of the patients blood into the Neutrocheck device and then comparing the intensity of the assay line to a visual score card. An app on a phone is also used to take a photo of the assay to produce an automated score. These are both done on the fist patient visit. There are no subsequent visits.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. At risk of neutropenia or neutropenic sepsis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Evidence of end-organ dysfunction or too unwell to use the Neutrocheck device (e.g systolic blood pressure < 90mmHG)
2. Known HIV or an active Hep B or Hep C infection
3. Bleeding disorder in which a finger prick test is contraindicated
4. Acute Myeloid Leukaemia
5. Significant visual impairment or blindness
6. Participants with significant manual dexterity issues that would prevent them from completing the test

Date of first enrolment
18/03/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
52North

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
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 1.3	13/03/2025	18/07/2025	No	Yes