

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/07/2025	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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 C reactive 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 March 2027

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

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Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

331579

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 61264, Grant Codes: 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

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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

Study design

Interventional non-randomized

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See study outputs table

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

Phase

Not Specified

Primary outcome measure

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 first patient visit. There are no subsequent visits.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

02/02/2022

Completion date

18/03/2027

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

425

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

18/03/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

Sponsor details

Cambridge Biomedical Campus, Hills Road

Cambridge

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United Kingdom

CB2 0QQ

+44 1223217418

cu.h.research@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.cuh.org.uk/>

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

Innovate UK

Alternative Name(s)

innovateuk

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

52North

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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