PATIENT INFORMATION SHEET & INFORMED CONSENT FORM

NeutroD: Evaluation of the diagnostic performance of Neutrocheck® device compared with standard-of-care neutrophil and C-Reactive Protein readings in patients at risk of neutropenic sepsis.

You are being invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of this trial and what will happen to you if you take part. Section 2 gives you more detailed information about the conduct of the trial.

SECTION 1: PURPOSE OF THE TRIAL AND WHAT WILL HAPPEN

1. What is the purpose of the trial?

The aim of the NeutroD trial is to test the accuracy of a device called Neutrocheck in measuring levels of neutrophils and C-reactive protein (CRP) in the blood, compared to test results from the laboratory.

The trial will test the device on patients at risk of neutropenia within a hospital setting. Neutropenia is a condition which occurs when the body does not make enough neutrophils, which are a type of white blood cell essential to fight infections. A C-reactive protein (CRP) is a protein produced by the liver that can indicate inflammation or infection in the body. If a person with neutropenia develops an infection this can lead to neutropenic sepsis (NS) - a severe and potentially fatal condition.

Currently, all patients with suspected NS receive antibiotics intravenously within 1 hour of arriving in the hospital. During this hour, a blood sample is taken for analysis, to check neutrophil and CRP levels. Antibiotics are administered prior to the blood test result being available. However, not every patient with low neutrophils gets NS and need antibiotic treatment. If Neutrocheck is as accurate as hospital laboratory tests, this could lead to the possibility of patients testing at home. They would come into the hospital only if they were at a higher risk of developing neutropenic sepsis.

2. What is the device that is being tested?

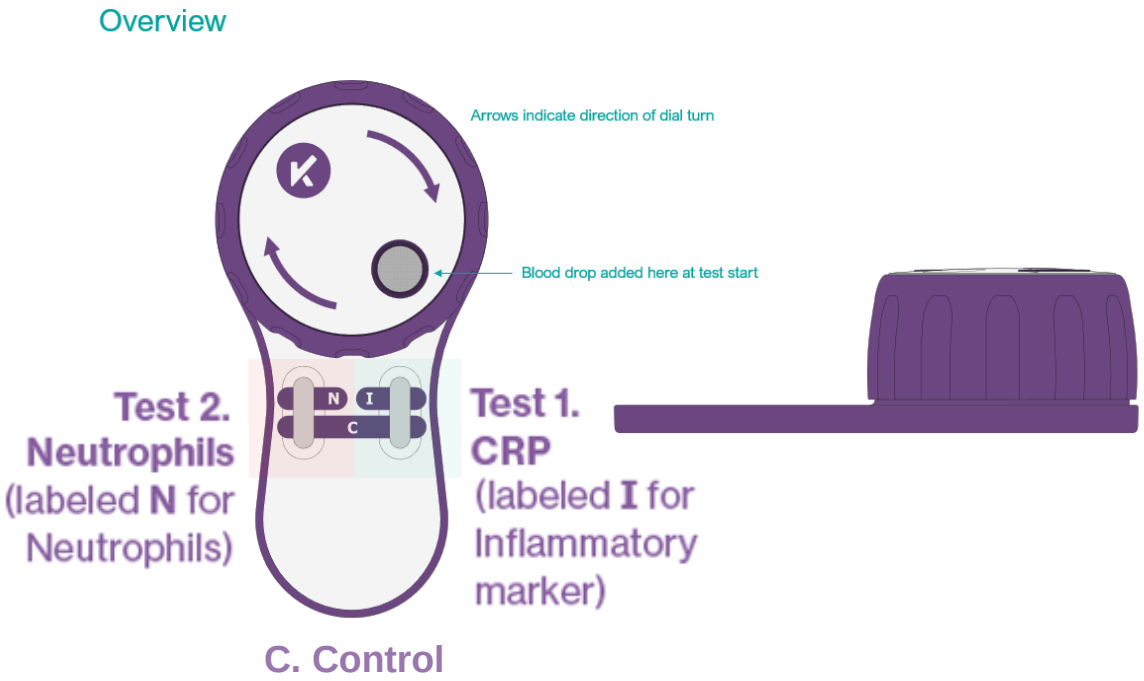
NeutroCheck is a medical device that measures neutrophils and CRP levels using the blood from a finger-prick. The device has been developed by 52North Health in Cambridge, UK.

This is the first study using NeutroCheck in patients. This device has not been approved by the Medicines and Healthcare Regulatory Authority (MHRA) but is available for use in research studies like this. This study is part of the process to get the device approved by the authorities in the future.

NeutroCheck should be stored at a temperature between 2-30 degrees celcius. Only with prolonged storage outside this temperature range (e.g. >24hrs) would we expect any effect on the stability or reliability of the devices.
They should be stored in a cool, dry place out of direct sunlight. E,g. a cupboard. Device storage should be avoided in environments where exposure to temperature extremes could occur, e.g. in a car.

Neutrocheck Instructional Video: https://youtu.be/jq8ebSjNib0

Figure 1: NeutroCheck device Front and side view



3. Why have I been invited?

You have been invited to participate in this study because you have been identified as a patient who is at risk of neutropenia or NS.

We plan to include 425 patients who are at risk of neutropenia or neutropenic sepsis and attend Cambridge University Hospitals NHS Foundation Trust, Addenbrookes Hospital.

4. Do I have to take part?

Taking part in this trial is voluntary. If you decide to take part, you will be asked to sign the Informed Consent Form. However, you are still free to withdraw after you agree to join this trial.

You can leave the trial at any time without giving a reason. However, it can be helpful to understand why as it can help the trial to reach conclusions that are more reliable when the team analyse the data at the end of the trial or may inform the design of future trials.

If you chose not to take part, change your participation or to leave the trial, your future medical treatment and normal standard of care treatment will not be affected in any way.

5. What will happen to me if I take part?

If you agree to participate in the trial, you will be asked to sign the Informed Consent Form at the end of this document and be given a copy of this to take away and refer to later.

After giving your consent, your trial doctor or nurse will check your medical history to make sure you are eligible to participate. Your vital signs such as blood pressure, pulse and temperature will also be checked and recorded. If you are eligible to participate in the study, you will use the device under the guidance of the study research clinician.

Blood will be taken, which will be tested for CRP and neutrophils at the pathology laboratory at Cambridge University Hospital, and separately by the company that provides the device (52North) at the Cancer Research UK Cancer Institute on the Cambridge Biomedical Campus. The NeutroCheck test will be then carried out under the guidance of a research clinician.

If you are attending:

I. **Cancer Assessment Unit (CAU)**: The test will be done in the CAU visit only, unless you are admitted to wards, where you will follow the process for patients admitted to wards.
II. **Wards**: Daily tests will be carried out until you are discharged from hospital
III. **Clinic Visit**: The test will be carried out in the regular clinic visits (at least 2 weeks apart) for a maximum of 6 months.

Standard of care process will be followed throughout the trial period for each participant, if abnormal blood levels are detected then it will be reported back as an incidental health related finding.

6. What will I have to do?

After having a maximum of two venous blood samples taken from your arm for each visit during the trial, 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 yourself with the device, you 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 your 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. You 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 you 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. You will be asked to complete a usability questionnaire after you complete the test.

The test takes approximately 20 minutes in total and will not be used in any way to determine treatment.

You should tell the trial team if you feel unwell or different in any way. If you have any major concerns or are feeling very unwell please let your trial doctor know immediately. If you feel unwell after leaving the CAU or hospital, please contact the trial doctor using the contact numbers at the end of this information sheet.

Blood samples will not be stored and will be disposed of according to local policy for safe handling and disposal of healthcare waste.

7. What are the possible disadvantages and risks of taking part?

- You may experience discomfort at the time of pricking your finger 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, you may have excessive bleeding from the finger-prick site. Study staff will assist you if this is the case.

- The risk of infection happening is very low. You will be given instructions about cleaning your hands and the finger-prick site, which will help to prevent this from occurring.
- In the days following participation in the study, if you notice your finger is red, hot or swollen you should seek medical advice. Should this occur, please inform the study team using the contact details on page 8 after you have received medical attention.
- Some people feel uneasy at the sight of blood and this may lead them to feeling faint or having a fainting episode. As part of this study, you will be required to produce a blood drop from a finger-prick and transfer the blood to the Neutrocheck device using equipment provided in the test kit.
- If you have a phobia of blood or have fainted at the sight of blood in the past, you should NOT take part in this study.
- Please let study staff know if you feel dizzy or unwell when you are participating in the study.
- Study staff will assist you if you feel unwell.
- Some people develop a mild reaction at the site of the finger-prick, from the plaster. Should this occur, please inform the study team.

8. What are the possible benefits of taking part?

There will be no direct benefit to yourself by 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.

9. How long will I be in the study?

Once you agree to take part in the trial, if you are attending:

I. **Cancer Assessment Unit (CAU):** The duration of participation in the study will be for this visit only, unless you are admitted to wards.
II. **Wards:** The duration of the participation will be daily use of the device until discharge from hospital.
III. **Regular clinic visit:** The duration of participation will be use of the device at every clinic visit for a maximum of 6 months.

10. Will I receive Expenses or Payment

You will not receive any payment for participating in this study and should not incur any expenses.

Section 2: Trial Conduct

11. What if I decide I no longer wish to participate in the trial?

You are free to withdraw from this trial at any time without giving a reason and without affecting your future care or medical treatment. Any data already collected or results from tests already performed on you will continue to be used in the trial analysis, unless you explicitly request otherwise.

The study research clinician may also choose to change your participation or withdraw you from the trial if they feel it is in your best interests or if you have been unable to comply with the requirements of the trial.

12. What if there is a problem?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. If you have any concerns about any aspect of this trial, you should speak to the study research clinician who will do their best to answer your questions.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can also do this through the NHS complaints procedure. In the first instance, it may be helpful to contact the Participant Advice and Liaison Service (PALS) at your hospital.

Complaints Department Contact Details: Cambridge University Hospitals Patient Advice & Liaison Service
Tel: 01223 216756
Email: cuh.pals@nhs.net
Address: Cambridge University, Addenbrooke's Hospital, Hills Road, Cambridge CB2 0QQ

In the event that something does go wrong, and you are harmed by taking part in the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust. If your claim is successful, your legal costs will be met. The normal NHS complaints mechanisms will still be available to you (if appropriate).

The NHS does not provide no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They can consider an ex-gratia payment in the case of a claim.

13. How will we use information about you?

Cambridge University Hospitals NHS Foundation Trust (CUH) is the Sponsor for this study based in the United Kingdom.

We will need to use information from you for this research study. The study research team will collect medical information about you and send it to the central NeutroD offices. In order to protect the confidentially of your health information, this information will be anonymised and linked to you only by a unique trial number allocated to you, so you cannot be identified from it.

The information that we keep about you will include name, age, ethnicity, NHS number, sex, and type of cancer. We will also collect information such as your blood pressure, pulse, temperature, date and time of last dose of antibiotic administration as well as the result of your hospital blood test. This information is required to help determine the accuracy of the device.

People will use this information to do the research or to check your records to make sure that the research is being done properly. All information collected about you as a result of your participation in the trial will be kept strictly confidential. Your personal and medical information will be kept in a secured database and be treated in the strictest confidence.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

We will also use anonymous direct quotes from you for any publications in the future, these quotations are for highlighting evidence of how the device works during the trial.

De-identified information about your health and care relevant to this trial may be made available for other research studies run by CUH and/or the University of Cambridge or other organisations. These organisations may be NHS or other public sector organisations, academic institutions, charities and commercial companies in the UK or abroad. Before your data is shared with other organisations all personal identifiers, such as names, addresses and dates of birth, will be removed. Making information from trials available for further research helps maximise the benefit of conducting trials and allows other researchers to verify results and avoid duplicating research. To facilitate this, some trial datasets are made available to researchers via a public online database and become "open data". Data are thoroughly de-identified before they are submitted to an open data platform and once the data are uploaded, we do not have control over how they are used.

As per current regulations, once the investigation has come to an end and the analysis has been reported to the regulatory authorities, essential trial documentation will be archived in keeping with the Sponsor's policy and applicable regulations for a period of 25 years.

14. What are your choices about how your information is used if you change your participation in the study?

- You can stop your participation in this trial at any time, without giving a reason, but we will keep information about you that we have already collected.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

15. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-participants/
- Our leaflet available from www.hra.nhs.uk/participantdataandresearch. Alternatively, please visit, for Cambridge University Hospitals NHS Foundation Trust: https://www.cuh.nhs.uk/participant-privacy/.
- By asking one of the research team
- By sending an email to cuh.gdpr@nhs.net or
- By ringing us on 01223 256141

16. How will results from the study be published?

When the results of this study are available, they may be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published in an approved, publically accessible online Clinical Trials Register. The results of the study will be anonymised and you will not be able to be identified from any of the data published.

The funder of the trial, 52North will be receiving study results. If you would like to obtain a copy of the published results please contact the study research clinician directly who will be able to arrange this for you.

17. Who is funding the trial?

The study is funded by a grant received from the Small Business Research Initiative (SBRI) and 52North. The medical device is provided free of charge by 52North.

18. Who has reviewed this trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given favourable opinion by East of England - Cambridge Central Research Ethics Committee.

Further information and contact details

If you have any questions concerning this study please contact any member of the Study Research Team:

Study Doctor:
Name: Hugo Ford
Tel: 01223 348481

Research Nurse:
Name: Lauren Simpson/Helen Whatling
Tel: 01223 216395, 01223 257071

In the event of an emergency please contact:

Contact: Saif Ahmad

Tel: 01223 245151

Alternatively, if you or your relatives have any questions about this study, you may wish to contact one of the following organisations that are independent of the hospital at which you are being treated:

CancerHelp UK is a registered charity providing information about all aspects of cancer. You can contact the specialist nurses on Freephone 0808 800 4040 (9am to 5pm, Monday to Friday). You can also access their web site at: www.cancerresearchuk.org/cancer-help/

MACMILLAN Cancer Support is a registered charity providing information about all aspects of cancer. They have published several useful booklets on different types of cancer, chemotherapy, radiotherapy, and clinical studies in general. You can contact the specialist cancer nurses on Freephone 0808 808 0000 (9am to 8pm, Monday to Friday). You can also access their website at www.macmillan.org.

Breast Cancer Care is a registered charity whose aim is to inform patients and their family members, healthcare providers and the wider community about dealing with breast cancer. You can also access their website at www.breastcancercare.org.uk.

Thank you for reading this leaflet and for considering taking part in the NeutroD study.

INFORMED CONSENT FORM

Study Title: NeutroD

Principal Investigator: _____ **Patient Number:** _____

	If you agree with each sentence below, please initial the box	**INITIALS**
1	I have read and understood the Patient Information Sheet version 1.3 dated 13/03/2025 for the above study and I confirm that the study procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care being affected.	
3	I understand that information related directly to my participation in this study may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel. I give permission for these individuals to have access to my records.	
5	I understand that the doctors in charge of this study may close the study, or stop my participation in it at any time without my consent.	
6	I understand that I will not benefit financially if this research leads to the development of the new diagnostic tool.	
7	I agree to carry out the test for this research study which involves a maximum of two venous blood samples being taken during each visit during the trial and pricking my finger with a lancet and squeezing my finger to get a drop of blood	
8	I agree to having one of my blood samples tested independently on another Neutrocheck device by delegated and appropriately trained members of 52North	
9	I understand that personal information such as my name, age, ethnicity, sex, NHS number and type of cancer will be recorded for this study. I give permission for study staff at Cambridge University Hospitals NHS Foundation Trust, to have access to my records.	
10	I understand that the de-identified data (data which cannot be traced back to me) from this study will be made available to other researchers and to the device manufacturer for commercial purposes	
11	I give permission for direct quotations to be used for publication purposes anonymously.	
12	I give permission for the research team to inform my GP of my participation in the NeutroD study.	
13	I have read and understood my responsibilities for the trial.	
14	**I agree to participate in the NeutroD study**.	

Name of patient | Signature | Date

_____ _____ _____

Name of person taking consent | Signature | Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the study team, 1 copy to be retained in the hospital notes.