REQUEST FOR PARTICIPATION IN MEDICAL EQUIPMENT TRIAL

DO YOU WANT TO PARTICIPATE IN THE RESEARCH PROJECT ULTRASOUND FOR MONITORING BLOOD FLOW DURING CARDIAC ARREST

This is a request to you as a relative to give consent on behalf of the patient to participation in a research project involving assessment of new medical equipment. The project aims to investigate whether the newly developed ultrasound probe "RescueDoppler" can measure blood flow in the carotid artery during ongoing cardiopulmonary resuscitation (CPR) for patients experiencing cardiac arrest.

This is the first time RescueDoppler is being tested on patients. The ultrasound probe system has received approval from the Norwegian Medicines Agency for clinical testing on cardiac arrest patients. The patient is invited to participate in the study because the patient recently experienced a cardiac arrest and received CPR from healthcare professionals at a hospital or an ambulance. During this event, measurements were taken using RescueDoppler. A patch with the probe was attached to the patient's neck, that continuously measured the blood circulation in the carotid artery during CPR, blinded to the health personnel.

The primary goal of the study is to investigate whether continuous monitoring of blood flow in the carotid artery using RescueDoppler is a sensitive method for measuring pulse. This could provide better diagnostic information and decision support regarding further treatment. The study is planned to last a little over a year. Depending on when the patient is included in the study, the data collected will be evaluated either against the functionality and user-friendliness of RescueDoppler for those performing CPR and/or to assess the medical information recorded by RescueDoppler during its use.

Cimon Medical AS is the company that developed RescueDoppler, and NTNU is responsible for the management of the research project.

We encourage you to carefully read this information and take the time you need to consider the patient's participation. The study physician can address any questions you may have.

WHAT DOES PARTICIPATION IN THIS STUDY ENTAIL FOR YOU?

Since it wasn't possible to obtain consent to study participation in advance, we are now seeking approval for participation retrospectively. This means that we have conducted measurements on the patient using the RescueDoppler, but you must consent on behalf of the patient to us including additional data about the patient in the study.

The information we have gathered in the study consists of blood flow measurements from the RescueDoppler. Additionally, we wish to gather information from the defibrillator used by healthcare personnel, data from other treatments related to CPR, as well as the following data from the patient's medical records: age, gender, past illnesses, medications, probable cause of your cardiac arrest, CPR outcome, and the healthcare provider's report on the cardiac arrest the patient experienced.

You and the patient's participation end when you have decided whether to consent to the inclusion of the patient's data in the study or not.

If the research project demonstrates that the RescueDoppler device could be beneficial, the results from the study may contribute to supporting the safety and efficacy of a future CE marking for similar devices. Beyond this, there will be no commercial exploitation of the patient or the patient's health information.

POTENTIAL BENEFITS AND DRAWBACKS

During the patient's resuscitation, measurements were conducted using RescueDoppler. Healthcare providers were not permitted to monitor RescueDoppler's measurements while administering CPR, thus its usage did not influence the medical care the patient received. These measurements did not subject the patient to any risks, disadvantages, or discomfort.

PARTICIPATION AND THE OPPORTUNITY TO WITHDRAW YOUR CONSENT

If you wish to consent on behalf of the patient, please sign the consent form on the last page. You may withdraw your consent from the study at any time and without providing any reason, it won't affect the patient's ongoing treatment.

If you agree on behalf of the patient to participate in the study, according to the European Union's General Data Protection Regulation (GDPR), you have the right to access the information recorded about the patient. This information will be provided within 30 days. You also have the right to object to and correct any inaccuracies in the information we have recorded. Additionally, you have the right to access information about the security measures in place for handling the patient's information. If you withdraw your consent from the study, no further information will be collected. Information already collected will not be deleted and may be used in further research within this study. You can file a complaint about the handling of the patient's information with the Data Protection Authority and the institution's Data Protection Officer.

If you later wish to withdraw or have questions about the study, you can contact the project leader Charlotte Ingul, by phone: +47 95 80 58 86 or email: charlotte.b.ingul@ntnu.no.

WHAT HAPPENS TO YOUR INFORMATION?

The information recorded about the patient shall only be used as described under the purpose of the study and as described in this information sheet.

All information will be processed without names and social security numbers or any other directly identifying details. A code links the patient to the patient's information through a name list. This means that the information is de-identified. The list that can connect the patient's name to the code will only be kept at the hospital the patient is admitted to, and only study personnel at the hospital will have access to this list.

The information collected about the patient in the study will be used within the study until the study concludes on December 31, 2025. For documentation purposes, the information will be retained for a minimum of 10 years after the project ends and will then be anonymized.

Publishing of results is a necessary part of the research process and is done on aggregated data, making it highly unlikely that the patient will be identifiable. We must inform you that we cannot rule out the possibility of it occurring.

Any extensions in the use and storage period can only occur after approval from the Regional Committee for Medical and Health Research Ethics (REK) and other relevant authorities.

SHARING INFORMATION AND TRANSFER ABROAD

As a part of the study, the collected information about the patient will be transferred to our partners in Spain at the University of the Basque Country for technical processing and analysis.

NTNU is responsible for ensuring that the transfer of information complies with Norwegian law and EU data protection regulations (GDPR). Only de-identified information will be transferred – the code linking you to your personally identifiable information will not be disclosed. The following information will be analyzed in Spain: blood pressure, electrocardiogram, blood flow, and compression depth during CPR. The data transferred will be stored with the Spanish research group, Bioengineering and Resuscitation (BioRes). Once the analysis is complete, the results will be returned to Norway and project leader Ingul.

ADDITIONAL CONSENT AND FUTURE RESEARCH

During the RescueDoppler study, information of significant value for other studies related to cardiac arrest will be collected. The main objective of these studies is to expand our knowledge of cardiac arrest in order to improve treatment for patients affected by it. The institutions involved in this study will serve as the responsible authorities for these studies.

Participating in other studies is purely voluntary and is in addition to participation in the RescueDoppler study. Directly identifying information about the patient will not be shared. If relevant, further details can be found in a separate informational document.

APPROVALS

The Regional Committee for Medical and Health Research Ethics at the Committees for Clinical Trials of Drugs and Medical Devices (REK KULMU) has evaluated study [582681] and has granted pre-approval.

You have the right to file a complaint about the processing of the patient's information to the Data Protection Authority.

CONTACT INFORMATON

NTNU and project leader Charlotte Ingul are responsible for the privacy measures of the study. We process information about the patient for purposes related to scientific research, and because the research project has been assessed to be in the public interest.

The processing of personal data is based on the legal basis of the General Data Protection Regulation (GDPR) Article 6(1)(e), cf. Article 6(3)(b), cf. Article 9(2)(j), cf. the Personal Data Act §§ 8 and 9. Consent is obtained in accordance with the Health Research Act § 13.

On behalf of NTNU, the privacy services at Sikt - Knowledge Sector's Service Provider, have assessed that the processing of personal data in this project complies with data protection legislation.

If you have any questions about the study, experience unwanted events or side effects, or wish to withdraw from participation, you can contact [insert name and phone number of PI, and/or other permanent contact person].

If you have any questions about the privacy of the study, you can contact the institution's data protection officer at: [insert email address].

Further information about the study can be found in Chapter A – detailed explanation of what the study entails.

Additional information about privacy, finances, and insurance can be found in Chapter B – Privacy, finances, and insurance.

The consent form follows Chapter B. – Signed by the participants relatives consenting to participate in the study. The individual who has provided information about the study can confirm that the information has been provided.

CHAPTER A – DETAILED EXPLANATION OF WHAT THE STUDY ENTAILS

In the RescueDoppler project, we aim to test a new ultrasound technology that can continuously measure blood flow and provide information about the presence or absence of blood flow during cardiac arrest. The ultrasound probe is attached to the neck with a patch. Currently, there is only a 10% survival rate for cardiac arrest, highlighting a strong need for better monitoring of blood flow to make rapid decisions and optimize patient treatment.

During cardiac arrest, healthcare professionals must quickly determine signs of life and initiate CPR. Assessing blood flow during CPR is typically done by palpating for a pulse, which can be time-consuming and challenging. Minimizing interruptions in chest compressions is crucial for effective CPR, but pulse palpation requires stopping chest compressions. Every second without compression is detrimental, making a reliable method for detecting a pulse vital. Although a defibrillator is used during CPR to monitor the patient's electrical activity, it does not provide information about blood flow. Without blood flow measurement, emergency personnel face challenges, as pulse palpation is difficult and inaccurate. Knowing whether the patient has their own blood flow can determine whether chest compressions should be stopped or continued. Without blood flow measurement, it is challenging to assess when a patient has regained spontaneous circulation, whether chest compressions are effective, and to diagnose the correct cardiac arrest rhythm. Blood flow measurement can optimize treatment and lead to quicker and more accurate decisions. Monitoring should not require ultrasound expertise, and blood flow registration must be continuous and "hands-free."

Automated data analysis of blood flow registration must provide rapid and straightforward responses with minimal delay for emergency personnel.

Therefore, we have developed RescueDoppler, capable of continuously measuring blood flow from the carotid artery, an innovation developed by ultrasound engineers at Cimon Medical AS and NTNU. The RescueDoppler research group has tested and developed probe technology in an animal experiment showing promising results in under two years.

This could potentially impact survival after cardiac arrest. Animal experiments have shown that with the help of RescueDoppler, spontaneous rhythm can be detected without interrupting chest compressions, providing a more reliable diagnosis of cardiac arrest rhythm and measuring the effectiveness of chest compressions.

We aim to assess the clinical utility of this new technology. Therefore, we plan to include patients with cardiac arrest inside or outside the hospital continuously over a period of one year. A total of 320 patients are estimated to be included.

This is the first time RescueDoppler is being tested in a clinical setting. This means that the ultrasound probe itself is not CE approved yet.

As a relative of the study participant, you will be informed as soon as possible if new information becomes available that may affect your desire to consent on behalf of the patient to participate in the study.

CHAPTER B – PRIVACY, FINANCES, AND INSURANCE

WHAT INFORMATION ABOUT THE PATIENT IS COLLECTED?

The information recorded about the patient includes the data collected about blood circulation from the ultrasound examination with RescueDoppler. Additionally, we will gather information from the defibrillator used by healthcare personnel, recorded data from treatments performed in connection with resuscitation, as well as the following data from the patient's medical records: age, gender, past illnesses, medications, likely cause of your cardiac arrest, CPR outcome, and a report from healthcare personnel about the cardiac arrest you experienced.

Representatives from NTNU, the Norwegian Medicines Agency, and regulatory authorities in Norway and abroad may be provided with study information and granted access to relevant parts of the patient's medical records. The purpose is to verify that the study information matches corresponding information in the patient's medical records. Everyone who has access to information about the patient is bound by confidentiality.

By participating in the study, you also consent on behalf of the patient to the transfer of de-identified information about blood pressure, electrocardiogram, blood flow, and compression depth during CPR to foreign countries as part of research collaboration and publication in accordance with the purpose stated initially. NTNU is responsible for ensuring that the transfer of information complies with Norwegian law and EU data protection regulations (GDPR).

FINANCE

This study is financed by the Norwegian Research Council and funds are distributed through the Norwegian company Cimon Medical AS and NTNU.

The healthcare professionals are paid for the time invested in the project according to agreements with participating hospitals. As a participant in the study, the patient will not have any expenses and will not receive financial compensation for participation.

Professor and physician Charlotte Björk Ingul is the project leader for the study. She is employed part-time as a medical advisor at Cimon Medical AS and has options on shares in the company but owns none today. She is also employed at NTNU and at St Olavs Hospital.

INSURANCE

The patient is insured according to the Patient Injury Compensation Act.

INFORMATION ABOUT THE STUDY OUTCOME

A description of the study will be accessible on www.clinicaltrials.gov. Upon completion of the study, you can contact the project leader to obtain information about the outcome. Approximately one year after the trial has concluded, a summary of the results will be available on www.clinicaltrials.gov. A summary of the study findings may also be presented at a conference or published in a journal.

I CONSENT ON BEHALF OF THE PATIENT TO PARTICIPATE IN THE STUDY AND TO THE USE OF THE PATIENT'S PERSONAL INFORMATION AS DESCRIBED

With this, I also confirm that I have received information about the study, that any questions have been answered, and that I have received a copy of the information sheet.

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Place and date. Relative of the participant's signature

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Relative of the participant's name in capital letters

CONFIRMATION THAT THE PARTICIPANT IN THE STUDY HAS BEEN INFORMED

I hereby confirm that information about the study has been provided.

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Place and date Signature

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Role in study