ST. OLAVS HOSPITAL
TRONDHEIM UNIVERSITY HOSPITAL

Norwegian Air Ambulance Foundation

WILL YOU PARTICIPATE IN OUR RESEARCH PROJECT

THE REBOARREST TRIAL?

The effect of blocking the aorta with a balloon during cardiac arrest outside the hospital

THE PURPOSE OF THE PROJECT AND WHY YOU ARE BEING ASKED

This is a question for you as the patient's next of kin as to whether you consent to data collected on the patient as part of the Reboarrest Trial being used within further research. The patient has been treated for cardiac arrest and at the time they were included in this research project. The purpose of the project is to see whether inflating a balloon in the aorta during cardiopulmonary resuscitation (CPR) would increase the chances of getting your heart to start again.

Adult patients who suffer a sudden cardiac arrest outside the hospital have been identified as suitable candidates to participate in this study. All patients are given advanced cardiopulmonary resuscitation as normal. In half of the patients, a catheter with a balloon at its tip is also inserted into the aorta at the groin. This process is known as REBOA. The balloon is inflated inside the aorta in order to improve the effect of the heart compressions. All other aspects of treatment and transport to the hospital are conducted as normal.

The REBOA technique is well established and used in other non-cardiac arrest patient groups, although primarily in patients who have already been admitted to hospital. The purpose of this information sheet is to provide you with more information about the project and what participation will entail for the patient.

The purpose of the study is to see whether this additional measure may improve the effect of CPR in order to help more patients to survive sudden cardiac arrest in the future.

The patient was not in a condition to decide whether or not they wanted to participate in the research project at the time when they received treatment. The Regional Ethics Committee (REC) in Norway has given its approval to start the project without consent under the condition that we ask for consent for further use of the data within research as soon as you or the patient themself is in a condition to answer the questions that we will ask in this document.

We are therefore turning to you as the patient's next of kin to ask whether we can use the data collected for the purpose of research. If the patient is able to give their consent within three months then we shall seek consent from the patient.

WHAT DOES THE PROJECT ENTAIL FOR THE PATIENT?

Half of the patients will have a REBOA catheter inserted into the aorta at groin level in combination with ordinary advanced cardiopulmonary resuscitation (CPR). As a participant in this project, the patient has therefore already been given advanced treatment for cardiac arrest, either with or without this additional measure. The patient has not been deprived of any treatment which they would otherwise have received.

In addition to collecting data from their cardiac arrest treatment outside the hospital, we will also collect data about the patient for up to 30 days after their date of admission. We record what treatment has been given prior admission, medical information before, during and after treatment (e.g. heart rate, blood pressure, blood oxygen levels, etc), data on the continued course of treatment, routine blood samples, level of functioning, survival. We will also consult their medical records after one year in order to see how things have progressed for the patient as a participant in this project. During the first 30 days, we receive data directly from the doctors at the hospital and from medical records. The information collected after one year is taken from the patient's medical records.

POSSIBLE BENEFITS AND DRAWBACKS

The patient will not benefit personally from consenting to their data being used for the purpose of research. The insertion of a REBOA catheter during cardiac arrest may entail an increased level of risk but it may also improve the effect of treatment. Several studies show that there is little risk of serious complications associated with the insertion of this type of equipment. Any potential drawbacks from giving consent for the data to be used in research will relate to the storage and use of medical information about the patient. All sensitive information will be anonymised. This means that names and personal identity numbers will be stored in a list that only the researchers and supervisory authorities will have access to.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW CONSENT

Participation in this project is voluntary. If you would like the patient to participate then you may confirm this by signing the declaration of consent on the last page. You can later withdraw your consent at any time and without having to give a reason. There will not be any negative consequences for the patient or their treatment if you decide not to participate or later decide to withdraw your consent. If you withdraw your consent, then no further research will be conducted with regards to the patient's health data. You can also request that health data in the project be deleted or provided to you within 30 days. The right to request the deletion or provision of data does not apply in the case of information on any side effects or where data has been anonymised. Such rights may be limited if the data has been used in analyses that have already been performed.

If you would like to withdraw from the project at a later stage or if you have any questions about the project, then you can contact the project management team (see contact details on the last page).

WHAT HAPPENS TO THE DATA COLLECTED ABOUT THE PATIENT?

The data recorded about the patient may only be used as described under the section on the purpose of the project and is planned to be used up until 2030. Any extension to the period of use or storage can only be granted following the approval of REC and other relevant authorities. You are entitled to access data that are recorded about the patient and you are entitled to have any errors in the data corrected. You are also entitled to information about the security measures adopted in connection with data processing. You can lodge a complaint as to how the data are processed with the Data Protection Officer at the relevant institution.

Patient data will be stored for a period of five years following project conclusion in the interests of control.

THE SHARING OF DATA WITH OTHER RESEARCHERS

By participating in this project, you give your consent for anonymised data to be transferred to others both in Norway and abroad in connection with collaborative research and publication. All shared data will be subject to legislation in the country that they are shared to and may be shared outside of the EU/EAA provided that this is done in line with the EU's General Data Protection Regulation (GDPR). REC does not have the authority to assess any subsequent use of data stored in a database abroad. Participant data can only be shared in relation to research within the same field/topic area.

The data set will be stored on a secure server for research data at St. Olav's Hospital for a period of five years. It will also be stored on HUNT Cloud which is a research platform for the controlled storage and analysis of research data.

It may become relevant to register anonymised data within future national or international databases for the purpose of storage and subsequent use in research. Any such registration of data will be voluntary and in addition to normal participation in the project. We will therefore ask you to tick a separate box for this on the last page if you wish to consent to data being included in any future database. It is the legislation in the country where data are stored which applies however the project managers shall ensure that data transferred to any databases abroad will be processed and handled in a secure manner.

All sharing of coded information (anonymised/pseudonymised data) will entail a small risk of backwards identification. This means that data sets or publicly available information are combined in new ways which allow the research participants to be identified. The risk of this is very small. Data may be shared with editors and peer reviewers prior to publication in scientific journals even in the case of participants where consent has been given for participation in the actual study but not for other types of data sharing.

INSURANCE

All participants are insured under the compensation scheme for patient injury through the *Norwegian System of Patient Injury Compensation (NPE)*.

FUNDING AND OWNERSHIP

The project is funded by the Norwegian Air Ambulance Foundation. There are no commercial interests involved in the study. The results of the study will be owned by St. Olav's Hospital.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has undertaken a research ethics assessment and approved the project. REC reference no. 152504.

The Clinic for Cardiovascular Medicine at St. Olav's Hospital, Project Manager Jostein Rødseth Brede and Senior Researcher Andreas Jørstad Krüger are responsible for data protection in this project.

All of our data processing is on the basis of your consent.

CONTACT DETAILS

If you have any questions about the project or would like to withdraw your participation, you can contact

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If you have any questions about privacy or data protection in connection with this project, you can contact the Data Protection Officer at St. Olav's Hospital: personvernombudet@stolav.no

CONSENT ON BEHALF OF THE PATIENT

☐ **I agree to participate in this project and consent to the patient's personal data being used in the manner described** (Tick box)

Place and date

Participant signature

Participant name in block letters

I CONSENT TO THE PATIENT'S PERSONAL DATA BEING SHARED WITH OTHER RESEARCHERS IN THE MANNER DESCRIBED

☐ **I consent that my data may be shared with other researchers for the purpose of collaborative research and in the manner described** (Tick box)

Place and date

Participant signature

Participant name in block letters