

Information for Patients about a Clinical Trial to Study the Efficacy of Early Therapeutic Hypothermia to Reduce the Risk of Brain Damage in Connection with Cardiac Arrest

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Research Organisation: Region Stockholm

Director of Research: Per Nordberg, Associate Professor, Consultant, Karolinska University Hospital, Solna

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You have been included in a clinical trial to study whether early therapeutic hypothermia in connection with cardiac arrest increases the potential for survival and recovery without permanent disability or brain damage. The brain is a sensitive organ that is quickly affected by lack of oxygen as the result of cardiac arrest. Early therapeutic hypothermia during CPR or shortly after the heart has restarted is a promising method for reducing adverse consequences that may affect the brain. The method of beginning therapeutic hypothermia onsite by inserting a catheter in the nostrils has been scientifically examined and shown to be safe by major studies.

This clinical trial, which will be conducted by researchers and staff employed by Region Stockholm in close collaboration with Karolinska Institutet, has been approved by the Swedish Ethical Review Authority. The trial will be conducted at various acute care units in Sweden, as well as a number of other European countries, to study whether early therapeutic hypothermia following cardiac arrest as the result of ventricular fibrillation reduces the risk of death and improves brain recovery more effectively than monitoring and controlling fever only.

You were included in the trial in connection with cardiac arrest. Because you were unconscious, we were unable to request your consent for participation in the trial. We have notified your next-of-kin that you were included in the trial. Individuals who have experienced cardiac arrest are randomised to one of two groups:

- 1) Controls, who are treated on the basis of current international guidelines
- 2) Those who are treated on the basis of current international guidelines, as well as receiving therapeutic hypothermia, initially by paramedics immediately after cardiac arrest and subsequently for approximately 24 hours

You have been included in the following group:

Any patient who participates in the trial is equally likely to be randomised to either group. Neither the patient, next-of-kin nor healthcare staff may choose or affect which group it turns out to be.

During the days immediately following cardiac arrest, we collected data about typical details and factors involving CPR performed onsite at the time of the event, as well as care provided at hospital.

Etikprövningsmyndigheten
2022-02446-01-287971
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PRINCESS2 - A Swedish-conducted Randomised European Multicentre Clinical Trial to Study the Efficacy of Early Therapeutic Hypothermia in Connection with Cardiac Arrest

All participants will be followed up for approximately 90 days after cardiac arrest at an appointment with a nurse or specialist. You will receive written notification of the appointment. Any other follow-up appointment or monitoring will comply with the plan that the hospital sets up at the time you are discharged. Any additional rehabilitation, care or examination, the need for which is identified by one of our doctors or nurses at a follow-up appointment after 90 days, will be provided in cooperation with you.

All information collected as part of this project will be processed confidentially and stored for at least ten years pursuant to EU Directives. Data about you as an individual patient will be encoded in such a way that only the Director of Research will have access to your identity. The overall information gathered from the trial will be used for research purposes only. All results will be reported such that nobody who reads them will be able to associate any of the data with particular patients. All participants will be covered by patient insurance. Region Stockholm is the personal data controller pursuant to the General Data Protection Regulation (GDPR), and you may request access to, and correction of, the information that has been collected. You are entitled to contact the Patient Advocate at Region Stockholm or the Director of Research below whenever you choose with any questions you may have. The Swedish Authority for Privacy Protection (IMY) is the supervisory agency for this trial.

Your participation in this trial is wholly voluntary. Your decision whether or not to participate will not affect your present or future care. You may consent to participate now and change your mind later on by contacting the Director of Research below. If you do not consent to use of the data collected about you for research purposes, it will be deleted.

Per Nordberg, Associate Professor, Consultant
Karolinska University Hospital, Solna

Feel free to contact the specialists or nurse below with any additional questions you may have.

Emelie Dillenbeck, Specialist, Anaesthesiology and Intensive Care
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Thomas Hermansson, Nurse, Anaesthesiology and Paramedicine
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CONSENT FORM

I hereby consent to participate in PRINCESS2, a clinical trial to study the efficacy of early therapeutic hypothermia in connection with cardiac arrest to reduce the risk of brain damage, as well as to provide the Director of Research with access to all information required to conduct the trial as long as confidentiality is maintained and my identity is not disclosed.

Patient

City and date:

Signature:

Doctor providing notification

Printed name:

City and date:

Signature:

Printed name: