

Information for you who have been treated in Intensive Care after a cardiac arrest. Study of the importance of body temperature after cardiac arrest – The TTM2-trial

Trial Sponsor: Region Skane, Sweden

Investigator: XX

Webpage: www.ttm2trial.org

You have experienced a cardiac arrest, been unconscious and now woken up. Fever is common after cardiac arrest but it is unclear whether this fever has an important effect on bodily functions. Nor is it clear if lowering the body's temperature below normal levels is beneficial. We have therefore performed a study to see if temperature control during the first days after cardiac arrest can prevent harm. The aim of this treatment is to prevent brain damage which may affect patients who have survived a cardiac arrest.

You have been treated with temperature control for 40 hours and have been sedated during this time.

Some research findings have indicated that it can be very important to avoid fever after cardiac arrest, but we do not yet know if cooling the body to levels below 37°C protects against brain damage, or what exact temperature to you use. This is the reason for the present study. You have been randomized (by chance) to a pre-defined temperature.

Since you have been unconscious we have not been able to ask for your consent until now. We have however talked to your relatives/legally designated representative and informed them about your participation in the study. We have collected information about your cardiac arrest and the care which has been provided in intensive care. We have also collected about 20 ml of blood for chemical analyses.

We are now collecting information about the care you have received in the ward and will contact you by telephone in one month's time. We will also invite you to a follow-up visit in about 6 months, and 24 month's time. We estimate that this follow-up will take a few hours in addition to travelling time. You, and a relative/close friend will receive reimbursement for any travel costs. We will ask for your consent to perform several different memory tests. If these tests indicate that you have any condition which might be helped by rehabilitation, we will refer you to a neurologist (a brain specialist) for further tests and treatment.

All information that has been collected will be coded and stored in an electronic data base that fulfils all the requirements for privacy, so that your personal information will be protected. The information will be stored for five years according to EU-regulations and handled so that no unauthorized persons can access it.

You are entitled to view the information and ask for them to be corrected if anything might have been recorded erroneously. All data collection is confidential. Research results (which are reported without any personal identifiers) will be published and it will not be possible to connect the results to you personally.

The blood samples which have been collected will be stored in a “biobank” and the all personal identifiers will be removed and substituted with a confidential code. The blood samples will be analysed for markers to study if we can find any biomarkers that can aid in in the prognosis of cardiac arrest patients in the future. It will not be allowed to use the blood samples for any other research without additional approval from both an ethical committee and yourself. (Swedish biobank law 2002:297)

It is completely within you right to decline participation in this study and all data collection will then be suspended. Data which has already been collected can be destroyed, if you wish. Even if you consent to participate now, you can withdraw consent at any time in the future. Your choice of whether to participate or not, will not impact your current care in any way. If you have any questions regarding the study you can contact your physician and nurse or contact XX (information below).

[According to Swedish Law], Region Skane is responsible for the confidentiality of your personal information. You can request a copy of the information which has been collected, and request changes if the information is incorrect. If you have any questions regarding your personal information you can contact Personuppgiftsombudet i Region Skåne, 291 89 Kristianstad.

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