Use of two defibrillators and double defibrillation in cases of out-of-hospital cardiac arrest for patients with ventricular fibrillation - a randomised pilot study - DoubleD-Trial

# Information for research participants

We would like to ask if you would be willing to participate in a research project. This document provides information about the project and what participation entails.

## *What is the project, and why do we want you to participate?*

You have been enrolled in a clinical trial to evaluate whether the use of 2 defibrillators (heart starters) in the event of cardiac arrest increases the chance of survival.

At the time of your hospitalisation, you were suffering from electrical chaos, known as ventricular fibrillation, in your heart muscle. In such cases, early defibrillation with a heart starter (precisely the treatment you received) is crucial to treat this electrical disturbance and restore the heart's normal electrical activity and pumping capacity.

In some people, this defibrillation fails to bring the heart back to its normal rhythm on the first attempt. However, there are promising studies showing that when early defibrillation fails, using two heart starters to defibrillate the heart from two directions can increase the chance of survival. The results of previous studies are promising, but have been deemed insufficient to change current routine treatment.

The aim of this study is therefore to see if this new method is better than the standard treatment and could potentially save more lives.

The study will primarily be conducted at ambulance units in Västra Götaland, Region Halland and Region Värmland. All participating ambulance staff have undergone special training for this purpose.

This clinical study is being conducted by researchers at Karolinska Institutet, Stockholm and has been approved by the Swedish Medical Products Agency and the Swedish Ethical Review Authority. The research principal for the study is Karolinska Institutet . "Research principal" means the organisation responsible for the project. The research has been approved by the Swedish Ethical Review Authority. The reference number for the review at the Swedish Ethical Review Authority is Ref. no. 2025-03532-01.

## *How is the project carried out?*

You were included in this study at the place where your cardiac arrest occurred (outside a hospital), while you were in cardiac arrest. As you were unconscious at the time, we could not ask for your consent to participate. You were randomly assigned to one of two study groups. Neither you, your family members, nor your carers had the opportunity to choose the group to which you were assigned, nor influence that decision in any way.

The two study groups are:

1) The control group, members of which receive defibrillation with a heart starter based on current international guidelines
***or***
2) The intervention group, treated with defibrillation using 2 heart starters.

Both groups receive otherwise identical emergency treatment. No changes compared to routine treatment are made to other subsequent treatment in the ambulance or in hospital. All patients taking part in the study will subsequently be followed up approximately 30, 90 and 180 days after the cardiac arrest, via a telephone call made by a specially trained physician or nurse. All other return visits/follow-ups are to be conducted entirely according to the follow-up plan that your hospital deems you need.

## *What will happen to your data?*

After your cardiac arrest, we collected routine data regarding many details and factors surrounding the cardiopulmonary resuscitation (CPR) and defibrillation provided at the scene of the cardiac arrest, as well as the care provided in hospital. You will also be contacted by phone by a specially trained nurse, who will follow up with you after 30, 90 and 180 days. The answers you provide during these conversations will also be collected.

All information collected as part of this project will be handled confidentially, and data will be stored for at least 10 years, pursuant to EU directives. Data relating to you as an individual patient will be coded, so that only the study's principal investigator will have access to the coding of your identity. Your answers and results will be processed in a way that ensures that unauthorised persons cannot access them. The information gathered from the study will be used solely for research purposes.

Karolinska Institutet is responsible for your personal data. According to the EU's General Data Protection Regulation, you have the right to access the information about you that is handled in the project free of charge and, if necessary, have any errors corrected. You can also request that your personal data be deleted (right to erasure) and that the processing of your personal data be restricted. However, the right to erasure and the restriction of processing of personal data does not apply when the data is necessary for the research in question. If you wish to access the data, please contact Principal investigator Gabriel Riva, tel. 08 5870 36 47. If you have any further questions, you are welcome to contact the study coordinators listed below at any time.

The processing of your personal data for research purposes is supported by the legal basis of public interest. Karolinska Institutet is the data controller for the study. If you wish to know more about how your personal data are processed, you can contact the Principal Investigator or KI's Data

Protection Officer at dataskyddsombud@ki.se. If you are dissatisfied with the way your personal data has been processed, you have the right to file a complaint with the Swedish Authority for Privacy Protection at imy@imy.se, tel. 08 657 61 00

## *How can you get information about the results of the project?*

The results of this research will be published in scientific journals. All results will then be reported at the group level; that is, no one reading the results of the study will be able to attribute the data to one or more individuals.

## *Insurance and compensation*

Patient insurance applies to participation in this study.

## *Participation is voluntary*

Any further participation in this study is entirely voluntary. Your decision to participate in the study, or to opt out of participating, will in no way affect the continued care you need following your cardiac arrest.

Even if you give your consent now, you can discontinue your participation at any time by contacting one of the physicians or nurses in charge of the study (see details below), without having to give a reason. If you discontinue your participation at a later date, this will also not affect your continued care. If you discontinue your participation, no further follow-ups within the context of the study will be carried out.

## *The persons responsible for the project are*

Gabriel Riva, Specialist in Cardiology, Research Director,
Center for Resuscitation Science, Karolinska Institutet (Sponsor).
Email: gabriel.riva@ki.se, Telephone: 08-587 03 647

Akil Awad, Specialist in Anaesthesia and Intensive Care. Principal Investigator,
Center for Resuscitation Science, Karolinska Institutet.
Email: akil.awad@regionstockholm.se, Tel: 08-16 10 00

## *If you have any further questions about the study, please contact the physician or nurse in charge of the study:*

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## CONSENT FORM

☐ I have received written and verbal information and have been given the opportunity to ask questions about my participation in the double defibrillation study.

☐ I agree to take part in the double defibrillation study, which studies the effect of using 2 heart starters or the traditional one heart starter to treat cardiac arrest caused by ventricular fibrillation, in order to increase the chance of survival. I authorise the responsible researchers to access the information needed to carry out the study, provided that confidentiality is maintained and my identity is not revealed.

☐ If necessary, I agree that the representatives of the sponsor and the relevant authorities (Karolinska Institutet, the Swedish Medicines Agency and the Swedish Ethical Review Authority) may access my relevant medical records in order to verify that the study is being conducted correctly. In such case, my data will be processed confidentially and in accordance with applicable data protection rules.

**Patient:**

Place and date: .....

Signature: .....

Clarification of signature: .....

**Informing physician or nurse:**

Place and date: .....

Signature: .....

Clarification of signature: .....