TIGER STUDY

High-Sensitivity Troponin I in Addition to Guideline-Based Care in Emergency Medical Service - an Open Randomized Controlled Trial

2025-05-15

NCT number:

Participant Information Sheet

Invitation to Participate

We are inviting you to take part in a research study. This document provides information about the project and what your participation would involve.

Summary of the Project

Participation in this study is voluntary, and you may withdraw your consent at any time. The study aims to investigate whether a specific heart-related blood test can be used in prehospital emergency care (ambulance services) to identify heart attacks earlier. If you agree to participate, you will be randomly assigned to either the control or intervention group. In the intervention group, the blood test will be analyzed in addition to the standard care that the control group receives.

The blood sample required for analysis is less than one drop (0.02–0.1 ml). It will be collected via a finger prick or from a vein in the arm. This procedure may cause minor pain or bruising, but it is a standard part of medical care. Whenever possible, the sample will be collected alongside routine blood sampling.

As part of the study, researchers will need to access your medical records to follow up on the diagnosis and treatment you received at the hospital. Patient data will be stored in a secure database managed by the study sponsor, AISAB (Ambulance Services in Greater Stockholm), part of Region Stockholm. Research data will be stored in a secure database at Karolinska Institutet, a collaborating institution. All personal data will be pseudonymized, and no unauthorized person will have access to the data.

What is the purpose of this project and why are you being asked to participate?

Heart attacks affect people of all ages and genders. Early identification is crucial to ensure rapid and effective treatment. Currently, only patients with changes on an ECG can be diagnosed before reaching the hospital. However, most patients with heart attacks do not show such changes and require further investigation at the emergency department, often involving a heart-specific blood test. This study aims to examine whether this test can be performed earlier—in the ambulance—before arrival at the hospital. You are being invited to participate because your symptoms may indicate a heart attack.

The sponsor of this study is AISAB, part of Region Stockholm, in collaboration with Karolinska Institutet. The study has been approved by the Swedish Ethical Review Authority (reference number: 2023-07919-01).

How will the project be conducted?

This is a **randomized controlled trial (RCT)**, which means you will be randomly assigned to either the control or intervention group after you provide consent.

If assigned to the intervention group, you will give an additional small blood sample for the heart-specific test. The result of this study may help improve care for patients with similar symptoms in the future. No blood samples will be stored, and all data will be pseudonymized. Medical records will be reviewed by researchers for follow-up on your hospital treatment and diagnosis.

Potential Risks and Benefits of Participation

Participation is voluntary. If you feel discomfort or change your mind, you may withdraw at any time, even after care has been provided or data has been collected. This will not affect your ongoing care or your relationship with your care providers.

The potential risks are minimal, and the study is expected to benefit future patients through earlier detection and treatment of heart attacks. The blood test involves a finger prick or venous sampling, which may cause slight discomfort or a small bruise. Blood samples will be taken in connection with routine care whenever possible.

What happens to my information?

The project will collect and register personal information about you. Researchers will access your medical records to understand your treatment and diagnosis. The project collects two types of information:

- Follow-up data from your medical records – stored in a secure database at AISAB.
- Study data from forms completed by EMS personnel – stored securely via REDCap at Karolinska Institute.

Your data is protected by confidentiality laws. During data processing, your name and personal ID number will be replaced with a code. Only the study coordinator can link this code to your identity. Pseudonymized data may be published in scientific journals.

Your data is protected under the General Data Protection Regulation (GDPR). You have the right to access your data, request corrections, and—in some cases—request deletion. However, the right to deletion does not apply when the data is necessary for the scientific purpose of the study.

If you wish to access your data, contact:
Jakob Lederman, Lindhagensgatan 98, 112 18 Stockholm, Tel: 08-123 131 89
Data Protection Officers:

- AISAB: 08-123 120 19

- Karolinska Institutet: 08-524 860 66
  If you are dissatisfied with how your data is handled, you may file a complaint with the Swedish Authority for Privacy Protection (IMY).

What happens to my blood sample?

The blood sample you provide will be analyzed immediately during your care in the ambulance. It will then be discarded according to standard medical procedures. No samples will be stored.

How will I learn about the results of the study?

Study findings will be presented at scientific conferences and published in journals. If you have further questions, please feel free to contact us.

Insurance and Compensation

No compensation is offered for participation. You are covered by the standard Swedish Patient Injury Insurance as with any other medical care.

Voluntary Participation

Your participation is entirely voluntary. You may withdraw at any time without stating a reason, and this will not affect your current or future care.

To withdraw, please contact the project lead:

Study Contacts

Principal Investigator: Jakob Lederman
Address: Lindhagensgatan 98, 112 18 Stockholm
Phone: 08-123 131 89
Email: jakob.lederman@regionstockholm.se

Consent to Participate in the Study

I have received oral and/or written information about the study and have had the opportunity to ask questions. I will retain a copy of the written information.

- I consent to participate in the study “High-Sensitivity Troponin I in Addition to Guideline-Based Care in Emergency Medical Service - an Open Randomized Controlled Trial”, and to provide an additional blood sample to be analyzed during prehospital care in the ambulance.
- I consent to the sharing of pseudonymized and de-identified data with research groups in Region Halland and Västra Götaland Region (VGR).
- I consent to the responsible researchers accessing my medical records in order to follow up on the care and diagnoses I have received.

Place and date	Signature:
	Printed name: