Cardioplegic Protection of the Heart

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Information for Research Participants

We would like to ask whether you would like to take part in a research project. This document provides information about the project and what participation involves.

What is the project and why are you being asked to participate?
In the spring of 2020, the COVID-19 pandemic broke out and healthcare services faced major challenges. Despite this, the operating theatre of the Department of Cardiothoracic surgery in Lund continued to perform surgeries at more or less the same frequency as before. The problem was that medications and protective equipment were no longer as readily available. Among these was the infusion solution (cardioplegia) used to stop the heart during cardiac surgery and to protect the heart during oxygen deprivation, which became unavailable, and alternative options had to be explored.

The "new" cardioplegia solution that was procured is a well-established cardioplegia used at other thoracic surgery departments both nationally and internationally. The "old" cardioplegia solution has been used for approximately 15–20 years in cardiac surgery in Lund, and there had never previously been any reason to replace this seemingly well-functioning cardioplegia until it became unavailable. The new cardioplegia solution was perceived to be at least as good as the old one, and today both cardioplegia solutions are used in thoracic surgery in Lund.

The aim of this study is to compare the cardioprotective effect of the two different blood cardioplegia solutions. The study will be conducted on 40 patients, divided into two groups of 20 patients each. Through the surgical registry, we have learned that you are scheduled to undergo coronary artery bypass surgery at the Department of Cardiothoracic surgery in Lund. Individuals undergoing coronary artery bypass surgery have been selected for this study. According to a pre-prepared randomization list, you will be randomly assigned to one of the two treatment groups.

The research principal for the project is the Department of Cardiothoracic and vascular surgery, Skåne University Hospital. The research principal refers to the organization responsible for the study.

How is the study conducted?
For you as a research participant, participation means that we will take blood samples on a total of seven occasions during your surgery and one and two days after your surgery. Each sampling occasion is estimated to take approximately five minutes. The blood tests we will analyze are specific markers of how your heart muscle is functioning after your cardiac surgery.

The additional amount of blood that will be collected is approximately 50 ml and will be drawn from your existing catheters or as a venous blood sample, for example from the bend of the arm. In order to store samples for future use in a biobank, seven samples of 4 ml each will be taken at the same time as the other blood samples.

Possible consequences and risks of participating in the study
We see no risks associated with participation in this study, as both cardioplegia solutions are well established and well tested in cardiac surgery in Lund.

What happens to my personal data?
The project will collect and register information about you. Your responses and results will be processed in such a way that unauthorized individuals cannot access them. The party responsible for your personal data is the Department of Cardiothoracic surgery, Skåne University Hospital, Region Skåne.

According to the EU General Data Protection Regulation (GDPR), you have the right to access, free of charge, the data about you that are processed in the study and, if necessary, to have any inaccuracies corrected. You may also request that your data be deleted and that the processing of your personal data be restricted. However, the right to deletion and restriction of processing does not apply when the data are necessary for the current research.

If you wish to access your data, please contact Leif Pierre, +46 46 171 664 or leif.pierre@skane.se. The Data Protection Officer can be reached at dataskydd@skane.se or +46 46 755 00 81. If you are dissatisfied with how your personal data are being processed, you have the right to submit a complaint to the Swedish Data Protection Authority (Datainspektionen/Integritetsskyddsmyndigheten), which is the supervisory authority (as of 1 January 2021, Datainspektionen is named the Swedish Authority for Privacy Protection).

What happens to my samples?
The samples collected in the study will be stored in coded form in a so-called biobank. The name of the biobank is Region Skåne 136/BD29, and it is located at Skåne University Hospital, Entrégatan 7, floor 10, 221 85 Lund. The principal (responsible organization) for the biobank is Region Skåne.

You have the right to decline storage of your samples. If you consent to storage, you also have the right to later withdraw (revoke) that consent. Your samples will then be destroyed or anonymized. If you wish to withdraw your consent, please contact Leif Pierre at +46 46 171 664 or leif.pierre@skane.se.

The samples may only be used in the manner to which you have given consent. If there is a desire to use the samples in a future study, this requires approval from the Swedish Ethical Review Authority following a new application.

How will I receive information about the results of the study?
If you wish to know your individual study results, they can be found in your medical record. If unforeseen findings are discovered, the responsible physician will take these into consideration and inform you. The study is expected to be completed by summer 2022, and if you wish to see the overall results, please contact the study coordinator, Leif Pierre, at +46 46 171 664 or leif.pierre@skane.se.

Insurance and compensation
In the event of injury in connection with care or monitoring within public healthcare, the study participant is entitled to financial compensation in accordance with the Patient Injury Act and the patient insurance scheme.

Participation is voluntary
Your participation is voluntary, and you may choose to withdraw from the study at any time. If you choose not to participate or to withdraw, you do not need to provide a reason, and this will not affect your future care or treatment.

If you wish to withdraw your participation, please contact the person responsible for the study (see below).

Persons responsible for the study

The person responsible for the study is Leif Pierre, Perfusionist, PhD,
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