Oslo universitetssykehus

Versjon 2.0

Consent
CRT implantation group:

New nonivasive method for evaluating acute response to cardiac ressynchronization therapy (NIME-CRT)

NCT ID not yet assigned

Unique Protocol ID: 218564

18.05.2023

WOULD YOU LIKE TO PARTICIPATE IN THE RESEARCH PROJECT NEW METHOD TO INVESTIGATE THE EFFECTS OF PACEMAKER TREATMENT?

PURPOSE OF THE PROJECT AND WHY YOU ARE BEING ASKED

This is a question for you about participating in a research project aimed at investigating which patients benefit from a type of pacemaker treatment. Doctors have determined that your heart has reduced pumping capacity, and that the contraction of the two main chambers (right and left ventricles) is not synchronized (i.e., out of sync). This leads to symptoms such as shortness of breath and reduced physical capacity. The treatment for this is called resynchronization therapy (CRT), often combined with a defibrillator (called CRT-D). Such treatment involves the implantation of a pacemaker that stimulates both the right and left main chambers of the heart simultaneously. In this way, the heart's pumping power improves, and so do the symptoms (shortness of breath, fatigue, reduced performance). For many, this is a very good treatment, but we know that unfortunately some patients who receive CRT according to current guidelines do not experience improvement.

You are receiving this letter because according to internationally accepted guidelines, you are planned to be treated with such a system (CRT, CRT-D). We are now conducting a study to see if we can better differentiate patients who benefit from the treatment from those who do not. We will investigate whether a relatively simple measurement method using a sensor on the earlobe can be used for this purpose. The sensor is called non-invasive, meaning that it should not be inserted into the body but attached to the skin and therefore should not cause any extra discomfort. We will use this measurement method to become better at selecting patients who should have such a pacemaker implanted in the future. In this way, we can prevent unnecessary and potentially harmful treatment.

WHAT DOES THE PROJECT INVOLVE FOR YOU?

After the implantation, you will lie in a room in the hospital ward for one night for monitoring and control of the pacemaker the next day. We will come to your room in the afternoon after the implantation to perform some measurements. We will then attach an ECG and a sensor on your earlobe and take measurements while we turn on and adjust the settings of the pacemaker. This is a harmless examination where the actual measurements take a few minutes.

After 6 months, you will be called in for a check-up, which is part of the standard routine for patients who are implanted with CRT, to see if it is working properly. At this check-up, we will also perform an approximately 30-minute ultrasound examination of your heart. This is a harmless examination that takes some extra time, but in return, you will get a better examination of your heart function, and the doctor can better see how your heart function has changed after you have received CRT.

If you do not wish to participate in the study, you will receive identical treatment. In any case, you will be called in for regular check-ups. Only the mentioned additional examinations after implantation and at the first check-up will be added if you wish to participate in the study.

In the project, we will collect and record information about you, and we will store the ultrasound images, ECG, and sensor signals.

POSSIBLE ADVANTAGES AND DISADVANTAGES

The study will not have direct benefits or significance for you or your treatment. The advantage is that we will become better at selecting who should have CRT implanted in the future and thus prevent patients from receiving unnecessary treatment with potential complications.

VOLUNTARY PARTICIPATION AND POSSIBILITY TO WITHDRAW YOUR CONSENT

Participation in the project is voluntary. If you wish to participate, you sign the consent form on the last page. You can withdraw your consent at any time without giving any reason. It will not have any negative consequences for you or your treatment if you do not want to participate or later choose to withdraw. If you withdraw your consent, your health information will not be further researched. You can also request that your health information in the project be deleted or disclosed within 30 days. The right to request destruction, deletion or disclosure does not apply if the information is anonymized. This right may also be limited if the information is included in performed analyses.

If you later wish to withdraw or have questions about the project, you can contact the project leader (see contact information on the last page).

WHAT HAPPENS TO YOUR INFORMATION?

The information recorded about you shall only be used as described under the purpose of the project and is planned to be used until 2032. Any extensions in use and storage time can only occur after approval from REK and other relevant authorities. You have the right to access what information is recorded about you and the right to have any errors in the information corrected. You also have the right to access the security measures when processing the information. You can complain about the processing of your information to the Data Inspectorate and the institution's privacy ombudsman.

All information will be processed without name, date of birth, or other directly identifying information (= coded information). A code links you to your information through a name list. Only project leader Espen Remme and employees associated with this project have access to this list.

Information about you will be stored for five years after the end of the project for control purposes.

INSURANCE

As a participant in the study, you are insured in the usual way through the Norwegian Patient Injury Compensation (Norsk Pasientskadeerstatning).

APPROVALS

The Regional Committee for Medical and Health Research Ethics (REK) has made a research ethics assessment and approved the project (REK case number 218564).

Oslo University Hospital and project leader Espen Remme are responsible for privacy in the project.

We process the information in accordance with the EU General Data Protection Regulation Article 6 (1) (e) and Article 9 (2) (j) and your consent.

CONTACT INFORMATION

If you have questions about the project or want to withdraw from participation, you can contact project nurse Kari Melberg (email: kmelberg@ous-hf.no, phone: 48003805) or project leader Espen Remme (email: espen.remme@medisin.uio.no, phone: 23071413).

If you have questions about privacy in the project, you can contact the privacy ombudsman at the institution: personvern@oslo-universitetssykehus.no.

The Data Inspectorate's email address is: postkasse@datatilsynet.no.

I AGREE TO PARTICIPATE IN THE PROJECT AND THAT MY PERSONAL INFORMATION IS USED AS DESCRIBED.

Place and date

Participant's signature

Participant's name in printed letters

Consent

CRT control group:

New nonivasive method for evaluating acute response to cardiac ressynchronization therapy (NIME-CRT)

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PURPOSE OF THE PROJECT AND WHY YOU ARE BEING ASKED

This is a question to you about participating in a research project aimed at investigating which patients benefit from a type of pacemaker treatment, called resynchronization therapy (CRT). You have recently had such a CRT pacemaker implanted and will be called in for a 6-month check-up. You are receiving this letter because we want to try out a new method of measuring heart function to look at the effect of CRT on your heart. We want to try this measurement method at your 6-month check-up. It is a relatively simple measurement method with a sensor on the earlobe that we will try out. The sensor is called non-invasive, meaning that it should not be inserted into the body but attached to the skin and should therefore not cause any extra discomfort. The sensor should only be on during the CRT control itself while the doctor tests and adjusts the pacemaker settings. We will use this measurement method to become better at identifying patients who should have such a pacemaker implanted in the future. In this way, we can prevent unnecessary and potentially harmful treatment.

WHAT DOES THE PROJECT MEAN FOR YOU?

The method being investigated will potentially be used to improve the diagnosis of future patients, so the study will not have any practical impact on your treatment. If you are willing to participate, you will be called in for a 6-month check-up of the pacemaker at Rikshospitalet where you had it implanted. In addition to the regular pacemaker check-up, we will make the measurements with the sensor and perform a 30-minute ultrasound examination of your heart. This is a harmless examination that takes some extra time, but you will in return get a better examination of your heart function, and the doctor can better see how the heart function has changed since you received CRT. In the project, we will collect and register information about you, and we will store ECG, sensor signals, and ultrasound images. If you do not want to participate in the study, this will not have any impact on your further checks and follow-up. You will then be called in for a regular 6-month check-up.

POSSIBLE ADVANTAGES AND DISADVANTAGES

The study will not have direct benefits or significance for you or your treatment. The advantage is that we will become better at selecting who should have CRT implanted in the future and thus prevent patients from receiving unnecessary treatment with potential complications.

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