

Implementation of a Trimodal Prehabilitation Program as a Preoperative Optimization
Strategy in Cardiac Surgery and Heart Transplant

NCT03466606

Information for patients and Informed consent Form,

- Sub-project#1: Patients awaiting heart transplantation.

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INFORMATION FOR PATIENTS AND INFORMED CONSENT FORM

Research Project: **Implementation of a trimodal prehabilitation program as a perioperative strategy in cardiac surgery and heart transplantation.**

Sub-project#1: Patients awaiting heart transplantation.

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Center: Hospital Clínic

PATIENT STUDY NUMBER: _____

GENERAL DESCRIPTION OF THE STUDY:

We are inviting you to participate in this study because you are waiting for cardiac transplantation. This study aims to investigate how to improve your physical condition before surgery can get you have fewer complications and a faster recovery after surgery.

Before you decide whether or not to participate in this study, you must understand the requirements, as well as potential risks and benefits from your participation. In this document you can find information about the study. We ask you to read it carefully. You may not understand some words or phrases on it, please do not hesitate to ask any member of the investigation team for clarifications. If you decide to enroll into this study, we will ask you to sign this document and you will have a copy of it.

Cardiac surgery is a highly complex and stressful procedure for the body. That you arrive well prepared for surgery and recover quickly is very important for both you and your doctors. Previous research coming from other types of surgery consisted of a physical training plan, nutritional support and psychological support (prehabilitation) prior to surgery reduces complications after surgery and accelerated postoperative recovery. Furthermore, the adoption of healthy lifestyle habits will surely have a beneficial effect on you both before surgery and in the years after, extending your life expectancy.

PURPOSE OF THE STUDY:

This study aims to prove that the implementation of a multimodal prehabilitation program can achieve faster recovery and reduce complications after cardiac surgery

STUDY PROCEDURES

1. *Purpose of the study:*

The main objective of the study in which we invite you to participate is to demonstrate the feasibility and effectiveness of a multimodal prehabilitation program in cardiac surgery, in terms of improving aerobic capacity, symptoms and quality of life as well as reducing the incidence of postoperative complications and hospital stay after surgery.

2. *What does it mean for me to participate in the study?*

If you agree to participate in this study, first of all your functional status, quality of life, level of physical activity, and nutritional status will be evaluated by our team at the Hospital Clinic in Barcelona.

Compared to standard clinical practice, your participation in the study involves:

- 1) The completion of a comprehensive evaluation that aims to measure the capability of your heart and lungs to face surgery. Most of these tests are already routinely performed on all heart transplant candidates. Participating in the study will involve repeating these tests 2 more times (with an interval of 6-8 weeks) to confirm the effect of the training.
 - a. The walking tests consists of taking a 6-minuts walk that will allow us to evaluate your functional capacity. This test is related to your ability to perform daily activities. The sit-to-stand test is a 30-second test to assess your lower body strength and you will simply need to repeatedly get up and sit down from your chair.
 - b. During the cardiopulmonary stress test you will use a device like a stationary bicycle. This is a **non-invasive** test that aims to assess both your cardiovascular and respiratory function at rest and during exercise. During the test you will be pedaling for 8 to 10 minutes on the stationary bicycle. We will monitor and record your heart and respiratory rates as long as other parameters. A doctor will be monitoring you and making sure you perform the test under utmost safety conditions. You will be performing this test twice with different resistance on the bicycle each time. Complications related to this test are minimal and the mortality

risk is similar to that reported with other exercise tests. The test will last one hour approximately and does not require hospital admission.

2) We will ask you to complete a health **survey**, as long as questionnaires regarding your psychological state and physical activity level (20 minutes).

3) Nutritional assessment: you will complete a questionnaire regarding your eating habits. This questionnaire will provide us with information about what you eat and how many calories and protein you take from your regular diet. Results will be evaluated by a nutrition specialist.

Three months after surgery, we will meet you again to see how you are doing and repeat the assessments you did before surgery to see how you have recovered physically and mentally.

Once your exercise capacity has been determined you will participate in a training program that will be personalized based on your fitness condition, and will be supervised by doctors and physiotherapist. The study cardiologist will determine what type of exercise is safe for you. The exercise program will be carried out partially in the hospital facilities where you will have to go between 1 and 3 times a week, and the rest of the exercise program can be performed in the community. If you have a “smartphone” you will be offered the possibility of carrying a remote exercise and heart rate monitoring device to safely monitor your daily physical activity. Our professionals will be able to follow the exercise you do every day through a web platform where the data recorded by the mobile device will be saved.

You will be asked to do activities such as stretching, walking, stationary bike resistance exercise, and balance with the exercise specialist to improve your strength and ability to move. These exercises have been prepared by hospital physiotherapists and can be adapted to your needs. You will also be given some instructions on how to exercise your lung, arm and legs. Weight training will also be carried out under the supervision of physiotherapist and sport medicine specialists.

Additionally, during the program you will be advised by a nutrition specialist in group or individual sessions according to the initial assessment carried out and your needs. You

may require oral daily nutritional supplements. These ingredients have been shown to facilitate wound healing.

You will receive an initial personal interview with a therapist specialized in mindfulness psychotherapy lasting approximately 1 hour. From then on you will have the possibility of attending weekly mindfulness group therapy. Mindfulness therapy consists of providing tools to alleviate any anxiety you may have, coping strategies and postoperative expectations, with the aim of optimizing psychological well-being and ways of coping both before and after surgery. Your active participation in the healing process will also be discussed.

3. ¿ What are the disadvantages and risks of participating in the study?

The risk that you experience any heart problems during the walking and the cardiopulmonary stress tests is minimal. A doctor will be monitoring your heart at all times during these tests to ensure that the intensity of the exercise is safe for you.

The amount of exercise during the physical training phase will be prescribed by a cardiologist specialized in sport medicine and supervised by a doctor. There is a slight chance that you may experience some physical and emotional problems while completing the program. If this occurs, you must inform the study doctor and appropriate steps will be taken to ensure that you receive appropriate care. At any time during the training program you feel any discomfort, you will be treated immediately.

By agreeing to participate in this project, you are not waiving any of your legal rights or exempting the researchers or the institution from their civil and professional responsibility.

4. What happens if I decide not to participate

Nothing. Your participation is voluntary and free. You may withdraw from the study at any time without affecting your relationship with your doctor.

CONFIDENTIALITY

The processing, communication and transfer of personal data of all participating patients in this study will comply with the provisions of Organic Law 15/1999, of December 13, on the protection of personal data.

The data will be collected in a center research file and will be processed solely and exclusively within the framework of your participation in this study.

If you have a smartphone, it is possible to monitor your physical activity during the period of the program through a device called Nuubo care device nECG. This device, which is placed on the chest surface, records heart rate and electrocardiogram during exercise and sends the information to an application on your smartphone via Bluetooth. The data is stored encrypted on a server and only the research team will be able to access this information.

In accordance with what is established by data protection legislation, you can exercise your rights of access, modification, opposition and cancellation of data, for which you must contact your study doctor.

The data collected for the study will be identified by a code and only your study doctor/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be revealed to anyone except for cases of medical emergency or legal requirement.

Access to your personal information will be restricted to the study doctor/collaborators, health authorities (Spanish Agency for Medicines and Health Products), the Clinical Research Ethics Committee and personnel authorized by the promoter, when they need it to verify the data and procedures of the study, but always maintaining their confidentiality in accordance with current legislation.

Only the data collected for the study will be transmitted to third parties and other countries, which in no case will contain information that can directly identify you, such as name and surname, initials, address, social security number, etc. If this transfer occurs, it will be for the same purposes of the study described and guaranteeing confidentiality.

Patient consent form

Title of the study: **Implementation of a trimodal prehabilitation program as a perioperative strategy in cardiac surgery and heart transplantation**

Sub-Project #1: Patients awaiting heart transplantation.

Code: HCB_preHAB_Tx Cardiaco.

I, (participant name and surname).....

- I have read the information sheet that has been given to me about the study.
- I have been able to ask questions about the study.
- I have received enough information about the study.
- I have spoken with: (researcher name)
- I understand that my participation is voluntary.
- I understand that I can withdraw from the study:
 - Whenever I want.
 - Without having to give explanations.
 - Without this affecting my medical care.

- In accordance with the provisions of Organic Law 15/1999, of December 13, on the Protection of Personal Data (article 3, point 6 of Royal Decree 223/2004), I declare that I have been informed of the existence of a file or processing of personal data, the purpose of its collection and the recipients of the information.

- I freely give my consent to participate in the study.

Participant signature

Researcher signature

Date: ____/____/____

Date: ____/____/____

I would like you to communicate to me the information derived from the research that may be relevant to my health:

☐ SI

☐ NO

Participant signature

Researcher signature

Date: ____/____/____

Date: ____/____/____