CHRONOTROPIC RESPONSE, EXERCISE CAPACITY, AND CARDIAC DYSFUNCTION IN LIVER CIRRHOSIS PATIENTS

INFORMED CONSENT FORM

(Approved by the Committee on Ethics of the Federal University of Sao Paulo)

You are invited to take part in a research study about cardiac dysfunction in liver cirrhotic patients. You are being asked to take part in this study because you have liver cirrhosis, a condition associated with increased risk of cardiac dysfunction and exercise incapacity. Research studies include only people who choose to take part. Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. Your participation is voluntary; you will not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research, you may leave the study at any time, if you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with your doctor or with your hospital associated with Federal University of Sao Paulo.

This document describes all information about our study and what you should know during this evaluation. Your collaboration will be very important for us, but if you do not want to participate or give up any time, it will not result in any limitation of you treatment as well as no compromise of your follow-up. If you can not read this, someone will do it for you. Once you read this consent form and understand what your participation in this study, your decision will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

I,_____, resident in _____ _____, freely agree that I will volunteer in the study "Chronotropic response, exercise capacity, and cardiac dysfunction in liver cirrhosis". The main purpose of this study is to better understand how the heart in liver cirrhosis patients work during situation where the body need more blood to keep working, such as exercise and during liver decompensation. We wish to evaluate exercise capacity by using the six-minute walking test and study blood biomarkers (like conventional exams done in laboratory) associated with worse cardiac performance, higher risk of hospital admissions, and mortality during follow-up.

I am aware that:

1- I will be submitted to an exam named contrast Doppler echocardiogram with strain study, which is commonly used as part of cardiac evaluation in patients in the waiting liver transplantation list. This exam is conduct in a traditional way, as have been done for many years and validated by regulatory organs. In this part of study, researchers will evaluate the basal function of heart. A small amount of saline and small bublles will be infect in one periphereal vein during this exam, no adverse effect is expect during this study.
2- I will be instructed to walk during 6 minutes in order to evaluate my physical capacity. This test is named Six-Minute Walking test. During this test, I will be closely watched by the principal investigator in case I present any symptom. There is no need of previous physical training, I can walk as slow as I need, and brief rest during the test is allowed. At the end of the test, the distance walked will be computed as well as my heart rate, blood pressure, peripheral oxigen saturation and respiratory rate.

If you have any question, you should contact:
Carolina Frade Magalhães Girardin Pimentel Mota, MD, PhD
GASTROENTEROLOGIA DEPARTMENT - RUA NAPOLEÃO DE BARROS, 715 –SAO PAULO - SP
TEL: (11) 55764050

3- Blood exam samples will be collected in order to evaluate Blood exam samples will be collected in order to evaluated serum biomarkers associated to cardiac compromise, liver decompensation, hospital admission, and mortality. The data will be stored in a password-protected computer and locked file. The blood and tissue samples will be stored in a at -80°C freezer. The data and samples and analyzed just for this study. These samples will not have your name or medical record on them.
4- Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor or with the hospital. Your decision to not participate will not result in any penalties or loss of benefits to you.
5- serum biomarkers associated to cardiac compromise, liver decompensation, hospital admission, and mortality. The data will be stored in a password-protected computer and locked file. The blood and tissue samples will be stored in a at -80°C freezer. The data and samples and analyzed just for this study. These samples will not have your name or medical record on them.
6- You will not be charged for any blood draw, storage of blood costs that are part of this research study. You will not receive any payment in case you agree participating this study.
7- Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with your doctor or with the hospital. Your decision to not participate will not result in any penalties or loss of benefits to you.
8- By singinig this form, you give your authorization for the use your information, without mentioning your name, in scientific records, papers, and medical meetings.

The principal investigator is Carolina Frade M. G. Pimentel Mota, MD, PhD. If you have any question about this research or experience any problems, you should contact the principal investigator at Rua Napoleão de Barros, 715, Gastroenterologia Department – São Paulo – SP, Tel: (11) 55764050. Any information regarding ethic question should be direct to the Research and Ethic Comitee of the Federal University os Sao Paulo – Rua Botucatu, 572 – 1º andar – n 14, 5571-1062, tel: 5539-7162 – E-mail: cepunifesp@unifesp.br.

In case of any harm related to study and exams performed, our institution, Federal University of Sao Paulo, will be responsible for ethical and financial issues according to recent legislation.

After read this document, I agree with the terms presented and sign this document.

Sao Paulo, / / .

_____	_____
Patient or responsible	**Principal Investigator**
ID _____	**CRM-SP 136100**

_____
Patient

Carolina Frade M G Pimentel
Principal investigator

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