COVER PAGE

GENESIS REGISTRY (Gender Specific Registry in Subjects hospitalized with Heart Failure in Santiago)

TRANSLATED INFORMED CONSENT DOCUMENT

(FROM THE ORIGINAL SPANISH VERSION TO ENGLISH)

The Original Spanish version was approved in January 31, 2023

by the Eastern Metropolitan Health Service Scientific Ethics Committee

in Santiago city, CHILE

INFORMED CONSENT DOCUMENT

GENESIS Registry- Gender Specific Registry in Subjects hospitalized with Heart Failure in Santiago

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PURPOSE OF THIS DOCUMENT:

The purpose of this information is to help you to make the decision to participate in a clinical registry, called the GENESIS Registry- Specific Gender Registry in Subjects hospitalized with Heart Failure in Santiago, led by the Foundation of the Chilean Society of Cardiology and Cardiovascular Surgery. The following information describes the study in which you have been invited to voluntarily participate, and your role as a participant.

The GENESIS staff-professionals will answer any questions you may have about the study. Please read carefully and ask questions about the following information.

RESEARCH OBJECTIVE: To describe the demographic, cardiovascular risk factor, socioeconomic, and clinical characteristics of patients hospitalized for heart failure .

Heart failure, is a prevalent disease in patients older than 65 years of age. Heart failure consists of an "inability of the heart to supply nutrients and oxygen to the different tissues and organs in the human body ".

There are different diseases that can cause heart failure, such as heart attacks, hypertension, diabetes, heart valve diseases, and some genetic or inherited diseases that affect the heart muscle.

The objective of this work is to determine and compare the different characteristics of women and men when they are admitted to the hospital with a decompensated acute heart failure in terms of: clinical presentation, decompensating risk factors, drug treatment on admission to the hospital, levels of specific markers of heart failure, and history of cardiovascular risk factors such as hypertension, diabetes, smoking, cholesterol levels, kidney function, coronary artery status, among others.

INVESTIGATION PROCEDURES

In the study in which you have been invited to participate, it is expected to include 500 consecutively patients, men and women (250 subjects at the Hospital DIPRECA and 250 at the Hospital UC Christus), during 1 year.

In this study, you will be invited during your hospitalization by one of the members of the study team. It could be the study principal investigator, or any of the sub-investigators or coordinators of the GENESIS study (Cardiology Unit Staff). One of them will give you this informed consent giving information about the purpose of the registry, and will answer any question you may have after you have read and analyzed the document. If you agree to participate, you and the principal investigator or sub investigator will sign this informed consent.

In this survey, sensitive data about you will be recorded, such as your ID, birthdate, and an estimation of the total economic income of your family group. Likewise, you will be asked about your level of education, your marital status, your work status, and your health insurance. The specific data regarding your illness, decompensating factors and tests upon admission will be obtained from your medical record.

In addition, the registry includes different questionnaires which are useful to determine specific features of your heart failure including the risk factors that may influence your future treatment and prognosis. These are: 1. Depressive symptoms questionnaire, to determine your mood, 2. Frailty, which provides information on the degree of physical compromise, weight loss, muscle loss that you may have, 3. Heart failure questionnaire to categorize your risk, and finally, 4. Quality of life survey, which delves into how you experience this disease, and how much it influences your quality of life.

This study don´t incorporate laboratory tests or blood samples. Only it incorporates the ones ordered by your doctor.

Within our registry you will be identified given by 3 capital letters: the first coming from your first name, and the second and third from your first (parental) and second (maternal) last names, followed by the number that corresponds to you in order of entry into the registry according to the numbering indicated by each hospital.

Never your name will be revealed. Complete confidentiality will exist regarding this survey, and only your researchers will access to the information.

RISKS

There will be absolute confidentiality of the data, which will be in a centralized database with restricted access.

There are no risks associated with your participation in the study. No intervention will be performed. The treatment indicated by your doctor will not be modified.

BENEFITS

The information obtained with your participation will be useful to know about heart failure reality in Chile, and will allow us to compare the form of presentation, decompensating factors, risk factors, and prognostic elements of this disease between men and women.

Currently in Chile, the information about heart failure in women is scarce. Most of the studies are carried out only in men. Women are excluded from trials. This study will give us real data about the similarities and differences of heart failure in both sexes.

COSTS

This study does not entail any associated cost for you.

CONFIDENTIALITY OF INFORMATION AND VOLUNTARIANNESS

The information obtained will be kept confidential. It is possible that the results obtained will be presented in medical journals and conferences, however, your name will never be known.

Your participation in this research is voluntary. You may refuse to participate without changing the quality of care in your medical attention. The study has been reviewed and approved by the Ethics Committee of the XXX Hospital, which guarantees its veracity and ownership.

QUESTIONS

If you have questions about this medical research, you can contact or call the physician in charge at your hospital:

HOSPITAL RED SALUD UC CHRISTUS: DRA. MONICA ACEVEDO. Contact telephone number: +56 9 92282617

HOSPITAL DIPRECA: DRA. PAOLA VARLETA. Contact telephone number: +56 9 95390767

If you have questions about your rights as a participant in medical research, you can also contact the ethics committee that analyzed and approved the study: The Eastern Metropolitan Health Service Scientific Ethics Committee, and the Scientific Ethics Committee of Health Sciences of the Facultad de Medicina Universidad Católica (CEC- Salud UC)

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Email: comite@cec-ssmoriente-adultos.cl Phone number: + 56 9 98328739/ + 56 9 81566931

Email: eticadeinvestigacion@uc.cl Phone number: + 56 9 55042397/ + 56 9 55048137

DECLARATION OF CONSENT

I have been informed about the purpose of this medical research, the procedures, risks, benefits, and my rights. I have understood that I can withdraw my consent any time during the study.

I sign this document voluntarily, without being forced to do so. I am not resigning any rights that assist me.

I will be informed of any new study-related information that arises during the study and that may have direct relevance to my health condition.

I have been informed that I have the right to reappraise my participation at my discretion.

At the time of signing, I am given a signed copy of this document.

SIGNS

Participant name and ID# :_____

Participating Signature:_____

Date:_____

If the patient could not sign, the patient representative or relative

Name and ID #:_____

Representative Signature:_____ ___

Date:_____

Investigator Name and ID #:_____

Investigator signature:_____

Date:_____

Delegate of the Director of the institution Name and ID #:_____

_____

Signature:_____

Date:_____