PVP-Guided Decongestive Therapy in HF 2 (PERIPHERAL-HF2)

NCT06495892

July 21st, 2021

Informed Consent form for patient.

This Informed Consent Form is for the patients who attend the research entitled ***Peripheral Venous Pressure-Guided Decongestive Therapy in Heart Failure* 2 *(PERIPHERAL-HF2)*** Study.

This Informed Consent Form has two parts:

Information Sheet (to share information about the research with you)

Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet Introduction

I am _____,

the chief researcher in the project ***Peripheral Venous Pressure-Guided Decongestive Therapy in Heart Failure 2 (PERIPHERAL-HF2)*** at _____.

We are doing research on venous pressure (the pressure in your collective veins) in heart failure. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

Purpose of the research

Heart failure is a chronic disease that causes long term disability and high risk of death. The majority of the symptoms of heart failure is due to excessive fluid collection in the body. One

of the most effective therapies in heart failure patients to alleviate troublesome symptoms are diuretics (urine forcers). These drugs force the patient to urinate and removes this excessive water from the body. Unfortunately, many patients are known to be discharged from the hospital without adequate excess fluid removal, due to the inaccuracy of assessment methods that evaluate whether the right amount of fluid is removed from the body or not. This residual excess fluid in the body is the chief determinant of early re-admissions to the hospital. We believe that we can estimate the need for excess fluid removal by a simple pressure measurement form one of your intravenous lines. If we prove that this approach predicts a better outcome in patients with heart failure, current treatment algorithms for heart failure will change in this direction.

Type of Research Intervention

This research will use your demographic data, blood tests and a pressure measurement from one of the intravenous lines that is already put into place. No new intervention will be done and no additional drug will be used in this study.

Participant selection

We are screening all adults hospitalized with heart failure to participate in the research.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change.

Procedures and Protocol

The data recorded in the hospital system during your stay in the hospital will be used and no new test will be done. After a period, your survival ore readmission status will be checked from national database.

Duration

The research takes place over 1 to 2 years, but your active presence will not be necessary after your discharge.

Risks

As there is no new intervention in this study, there is no added risk during the data collecting process. The healthcare workers will be looking after you and the other participants very carefully irrespective of your decision on giving consent about your data to be used in the study.

Benefits

There may not be any benefit for you, but your participation is likely to help us find the answer to the research question.

Reimbursements

Your participation is free. You will not be given any other money or gifts to take part in this research.

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you that will be published in a scientific journal or presented in a scientific meeting will be completely de-identified and will not have your name on it.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. It is your choice and all of your rights will still be respected.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact to me.

This proposal has been reviewed and approved by local ethical committee, which is a committee whose task it is to make sure that research participants are protected from harm. You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant_____

Signature of Participant _____

Date _____ Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND

Signature of witness _____

Date _____ Day/month/year

Thumb print of participant

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. My clinical and laboratory information will be used.

2. A pressure is measured from my intravenous line that is already placed.

3. My survival or re-admission status will be checked trough national database.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____ Day/month/year