Heart failure with preserved ejection fraction determination by exercise ultrasonography follow-up

Published: 25-05-2021
Last updated: 04-04-2024

The main objective of the HELPFulUP study is to investigate deterioration of the diastolic function towards HFpEF in individuals with pre-clinical LVDD The secondary objective is to relate the progression towards HFpEF to clinical characteristics...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON51990

Source
ToetsingOnline

Brief title
HELPFulUP study

Condition

- Heart failures

Synonym
Heart failure with preserved ejection fraction - Diastolic heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ERC consolidator grant

Intervention

Keyword: Deterioration, Exercise echocardiography, Heart failure, Left ventricular diastolic dysfunction (LVDD)

Outcome measures

Primary outcome

The deterioration of LVDD towards HFpEF (stage C/D heart failure), measured by (stress) cardiac ultrasonography assessing functional and structural parameters, combined with natriuretic peptide measurements and clinical evaluation.

Secondary outcome

Paramaters that are collected for exploratory etiological hypothesis generation and further phenotyping of the heterogeneous population of patients with deteriorating diastolic function and HFpEF. Parameters include clinical factors, echocardiography paramaters (such as global longitudinal strain of the left ventricle and the left atrium calculated from standard echocardiography images) and biomarker parameters that can help to explain what individuals in stage B heart failure are at high risk of progression to stage C/D heart failure. Promising blood biomarkers (e.g. omics related to vascular dysfunction) will be measured again, and promising new biomarkers, e.g. BNP measurements after exercise will be added. To further elaborate the cardiorenal syndrome within our cohort urine biomarkers will be measured.

Study description

Background summary

Heart failure with preserved ejection fraction (HFpEF) is a syndrome with numerous comorbidities, leads to high hospitalisation rates, and a low health-related quality of life. The pre-clinical stage is often characterized by left ventricular diastolic dysfunction (LVDD). The deterioration from LVDD to HFpEF is more common among women compared to men, whereas the prevalence of LVDD is equally distributed among both sexes. Currently, it is hard to predict which individual with (pre-clinical) LVDD (stage B heart failure) has an elevated risk of developing HFpEF (stage C or D heart failure).

Study objective

The main objective of the HELPFulUP study is to investigate deterioration of the diastolic function towards HFpEF in individuals with pre-clinical LVDD

The secondary objective is to relate the progression towards HFpEF to clinical characteristics and additional examinations, as well as to (repeated) biomarker measurements.

Study design

Longitudinal cohort study.

Study burden and risks

The participants selected for follow-up plus (stress) echocardiography will have one visit scheduled at the UMC Utrecht that will take maximally 90 minutes of their time. To the best of our knowledge, the ultrasound waves do not have a negative health effect, and patients are electrocardiographically monitored during exercise. For exercise testing there is a very low risk for fatal events or events occurring that require hospitalisation (event rate 1:10.000). The risks of a venous blood withdrawal are a local hematoma or infection, and a vasovagal response. We will also ask the participant to collect urine for routine measurement and biobank storage.
The potential benefits for participants is that clinically relevant cardiac abnormalities can be discovered in an early phase of the disease and thus facilitating early intervention and treatment. To facilitate such management, a report of the BNP values, ultrasound parameters and its interpretation and management recommendation will be sent to the patient*s own treating physician/general practitioner.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Participants of the HELPFul study with a baseline diagnosis of LVDD without clinical signs or symptoms of heart failure (stage B heart failure)
- Participants consenting to be contacted for follow-up studies of the HELPFul study
- Participants who are able to read and understand the Dutch language.
- Participants who are willing and able to provide written informed consent for participation in this study.
- Participants who agreed that results of the follow-up measurements are reported to the treating physician.

Exclusion criteria

- Participants who received a heart transplantation or left ventricular assist device (LVAD) in the period between baseline and follow-up.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2021
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	02-11-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL76102.041.21