The Metabolic Road to Diastolic Heart Failure (MEDIA) - Diastolic Heart Failure Study (DHF)

Published: 20-02-2012
Last updated: 01-05-2024

This study will address the mechanisms of DHF by identifying the role of biomarkers in the process of neurohormonal activation, cytokine activation and oxidative stress, the role of biomarkers at myocardial level in the process of cardiomyocyte cell...

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

Summary

ID

NL-OMON39049

Source
ToetsingOnline

Brief title
MEDIA-DHF-study

Condition

- Heart failures

Synonym
Heart Failure with Normal Ejection Fraction, Heart Failure with Preserved Ejection Fraction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Commissie;FP-7

Intervention

Keyword: Biomarkers, Diagnosis, Diastolic Heart Failure, Registry

Outcome measures

Primary outcome

To determine the specificity and the sensitivity of biomarkers for the

diagnosis of DHF.

Secondary outcome

The prognostic power of biomarkers relative to all-cause death, cardiovascular

hospitalization, death or cardiovascular hospitalization.

Study description

Background summary

Diastolic heart failure (DHF) accounts for more than 50% of all heart failure cases and portrays a high risk of morbidity and mortality. Currently, the diagnosis of DHF is based on signs or symptoms of heart failure, normal or mildly abnormal left ventricular ejection fraction (LVEF) and evidence of diastolic left ventricular (LV) dysfunction. (2). Contrary to their usefulness for the diagnosis of symptomatic diastolic LV dysfunction, natriuretic peptides are sub-optimal screening tests for pre-clinical diagnostic of LV dysfunction. Thus, there is no single biomarker that can accurately predict the development or validate the diagnosis of LV Diastolic Dysfunction.

Study objective

This study will address the mechanisms of DHF by identifying the role of biomarkers in the process of neurohormonal activation, cytokine activation and oxidative stress, the role of biomarkers at myocardial level in the process of cardiomyocyte cell growth and extracellular matrix turnover as well as the role of proteomic markers such as cardiomyocyte sarcomeric and cytoskeletical proteins in the risk of developing these major disturbances.
Integrating all DHF patients into a single database and biobank is necessary to achieve adequate DHF sample size, to guarantee uniform criteria for DHF diagnosis and to have shared platform for biomarker analysis. Over time, this database will be extended with novel biomarkers as well as novel imaging and

vascular function tests. Through these activities the DHF-Study will assemble a comprehensive database and biobank of common and novel biomarkers, imaging and vascular tests as well as clinical data relevant for DHF. This will contribute to better diagnostic tools to identify subjects with DHF and to predict prognosis.

Study design

At baseline, all major demographics, the medical history, use of medication and the risk factors will be collected. After this, a physical examination, ECG and echocardography are performed.
These tests are complemented by a routine bloodsample with testing for lipid-profile, glucose and insulin, hemoglobin, BNP and NT-proBNP. A supplementary bloodsample (50cc) and urinesample (10cc) are taken and transferred to the Biobank at the Centre d-investigation clinique (CIC) in Nancy (France). Samples are stored at the CIC until central analysis is performed.
At 3, 6 an 12 months the patients are contacted by telephone and outcomes (death (any cause), heart failure and other cardiovascular hospitalizations, heart failure and other cardiovascular death) are assessed.

Study burden and risks

There is no additionale risk to the patient to take part in this study. The single bloodsample can be taken as part as a routine bloodanalysis.

Contacts

Public
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit Medisch Centrum

Van der Boechorststraat 7
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients 18 years of age or older
Able and willing to provide freely given written informed consent including analysis of genomics.
Signs or symptoms of Heart Failure, preserved LVEF (>50%) and evidence of diastolic dysfunction: ;The ratio of early mitral valve flow velocity (E) and early TD lengthening velocity (E*), E/E*>15.
In the case that E/E* ratio is only suggestive of diastolic LV dysfunction (15>E/E*>8), additional non-invasive measures are required for the diagnosis of LV diastolic dysfunction. These consist of:
• Plasma levels of natriuretic peptides (NT-proBNP> 220 pg/mL or BNP > 200 pg/mL) OR
• Echo - blood flow Doppler of mitral valve - ratio of early (E) to late (A) mitral valve flow velocity (E/A) <0.5 and deceleration time (DC) > 280 ms OR
• Echo- blood flow Doppler of pulmonary veins - duration of reverse pulmonary vein atrial systole flow (Ard) and duration of mitral valve atrial wave flow (Ad) (Ard-Ad >30ms) OF
• Echo measure of left atrial volume index (LAVI) > 34 mL/m2 OR
• Echo measure of left ventricular max index (LVMI)> 109 g/m2 for women; 132 g/m2 for men) OR
• Electrocardiografic evidence of atrial fibrillation

Exclusion criteria

Patients with acute myocardial infarction
Recent trauma or surgery (< 3 months)
Hemodynamically significant valvular disease
Serious cerebrovascular disease or stroke in the last 3 months
Chronic dialysis
Chronic liver disease

Chronic infectious (bacterial or viral) disease
Any malignant concomitant diseases or a malignant disease in the last 5 years
Systemic inflammatory diseases, such as autoimmune diseases, connective tissue diseases or collagenoses
Pregnant women

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2012
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	14-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL38526.029.11