HELPFul

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21717

Source
Nationaal Trial Register

Brief title
HELPFul

Health condition

Diastolic dysfunction of the heart, eventually evolving into heart failure with preserved ejection fraction, Coronary vascular disease, including both macro- and microvascular coronary disease

Sponsors and support

Primary sponsor: nvt
Source(s) of monetary or material Support: Dutch Heart Foundation, CVON, Laboratory of Experimental Cardiology UMC Utrecht, Netherlands

Intervention

Outcome measures

Primary outcome

The primary outcome will be categorical: degree of LVDD and HFpEF yes or no

Secondary outcome

nvt

Study description

Background summary

Heart failure is a severe syndrome formed by two entities, systolic heart failure and diastolic heart failure. Currently the term ‘heart failure with reduced ejection fraction (HFREF)’ is used for systolic heart failure and ‘heart failure with preserved ejection fraction (HFPEF)’ for diastolic heart failure. Until recently it was thought that diastolic heart failure had a better prognosis because the pump function of the heart was maintained. Most research has therefore been in the area of systolic heart failure resulting in good biomarkers, such as BNP, and better treatment options. Recent literature has pointed out the severity of diastolic heart failure, for which current biomarkers are not optimal and treatment options remain inadequate. New medicine for diastolic heart failure is in phase II clinical trial setting, which brings hope for better treatment options. To treat the correct type of patient good diagnostic modalities are necessary. For diastolic heart failure echocardiography is the golden standard, though there is much debate concerning the cutoff value for the ejection fraction (a value for the pomp function of the heart) and which combination of echocardiographic abnormalities should classify diastolic dysfunction or heart failure. Wall motions of the left ventricle, together with the volume of the left atrium, are viewed as the most important parameters. The addition of a biomarker to this echo for improvement of the diagnosis would be of great value. This is the goal of HELPFul, to discover and validate a biomarker in the diagnosis of diastolic dysfunction and HFPEF. Recent data shows that the causes of HFPEF are different from HFREF. HFPEF mostly affects women, with persistent high blood pressure and diabetes. These risk factors appear to damage the endothelium (lining of the vascular wall) in the small blood vessels of the heart (microvasculature). As a result these small vessels will collaps, causing regional oxygen deficiency and thereby thickening and stiffening of the heart. Another hypothese is that micro-embolia (small clots) let go of artery sclerosis (erosion) and cause the small vessels to get clogged. This could also result in thickening and stiffening of the heart. For the biomarker discovery we will aim for these two hypothese which centre around the endothelium and the coagulation. We will study the transcriptoma (information) of cells released from the smalls vessels of the heart for information on the presence of diastolic dysfunction or HFPEF. Furthermore we will study the blood for information suggestion the presence of micro-embolia. Our biomarker discovery is mostly aimed at the endothelium and blood coagulation. Promising biomarkers will be validated.

Study objective

Sex differences in cardiovascular disease (CVD) have been widely acknowledged. Diastolic dysfunction of the heart, eventually evolving into heart failure with preserved ejection fraction (HFpEF) is common in women and has been neglected in cardiovascular research. Currently, it is hypothesized to originate from microvascular dysfunction in the small vessels of the heart leading to stiffness and filling problems. Diastolic dysfunction and HFpEF in

women is associated with marked increase of all-cause mortality, yet the disease is often unrecognized because of insufficient diagnostic tools. To be able to effectively prevent diastolic dysfunction and treat HFpEF patients in the future, development of screening tools for (early) diagnosis is crucial.

Study design

T=1

Intervention

Venapunction

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Patients in the cardiology outpatient clinic (CCN) who are being evaluated with an echocardiography because of screening or referral from a general practitioner

• Age >= 45 year

• Patient is willing and able to provide written informed consent for participation in this study

• The inclusion criteria for cases match the criteria for diagnosis of LVDD or HFpEF.

The inclusion criteria for the subjects included in the random sample are similar for cases irrespective of their echocardiography findings.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Patients from whom no informed consent is obtained

• Incapacitated adults: language barriers or other obstacles for full understanding of the study objectives

• Patients with former cardiac procedures.

• Patients with congenital heart disease

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	3000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 14-04-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50536
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5439
NTR-old	NTR6016
CCMO	NL57077.041.16
OMON	NL-OMON50536

Study results