

HELPFul

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21717

Bron

Nationaal Trial Register

Verkorte titel

HELPFul

Aandoening

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

Ondersteuning

Primaire sponsor: nvt

Overige ondersteuning: Dutch Heart Foundation, CVON, Laboratory of Experimental Cardiology UMC Utrecht, Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 pump 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 collapse, causing regional oxygen deficiency and thereby thickening and stiffening of the heart. Another hypothesis 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 hypotheses which centre around the endothelium and the coagulation. We will study the transcriptome (information) of cells released from the small vessels of the heart for information on the presence of diastolic dysfunction or HFPEF. Furthermore we will study the blood for information suggesting the presence of micro-embolia. Our biomarker discovery is mostly aimed at the endothelium and blood coagulation. Promising biomarkers will be validated.

Doel van het onderzoek

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.

Onderzoeksopzet

T=1

Onderzoeksproduct en/of interventie

Venapunction

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 \geq 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2016
Aantal proefpersonen:	3000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 14-04-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50536

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten