Heart Failure with Preserved Ejection Fraction HFpEF - a prospective cohort

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25965

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Heart Failure with Preserved Ejection Fraction

Ondersteuning

Primaire sponsor: Investigator iniciated
Overige ondersteuning: Investigator initiated

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Stratify the heterogeneous group of HFpEF patients to identify specific subtypes.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The diversity in clinical phenotypes and poor understanding of the underlying pathophysiology of heart failure with preserved ejection fraction (HFpEF) is the main reason why no effective treatments have been found yet. Targeted, instead of a one-size-fits-all, treatment seems the only promising approach for treating HFpEF. To be able to design a targeted, phenotype-specific HFpEF treatment, the matrix relating clinical phenotypes and underlying pathophysiological mechanisms has to be clarified.
Objective: Our goal is to build up a deep phenotyped HFpEF cohort, to be able to select the right patients for different HFpEF studies with the final goal of improving the understanding of the pathophysiology of HFpEF. The HFpEF cohort will allow us to understand the relationship between the different comorbidities and the clinical outcome.
Moreover, the HFpEF cohort will allow us to select the right patients to include in phase 2 and 3 medical trials.
Study design: This is a prospective, observational study. Clinical data resulted from routine clinical diagnostic tests of the patients referred to the HFpEF outpatient clinic and who signed the informed consent will be used for clinical research. Moreover, blood samples (for biomarker profiling and cell isolation (monocytes, neutrophils, T cells, extracellulaire vesicles and platelets)) and urine samples will be obtained. The clinical data, blood and urine samples will be obtained at the first outpatient visit as well as after one year follow-up. Furthermore, in the context of the “HFpEF-cohort perfusion and metabolism study” (NL57468.068.16 /METC162032), 20 control hypertensive control patient’s blood and urine samples will be included in our biobank. From the blood analysis we will also isolate cells (monocytes, neutrophils, T cells, extracellular vesicles and platelets). These hypertensive control patients do not have HFpEF and will not be further followed up.
1. Use of clinical parameters obtained from routine clinical care of all patients referred to the HFPEF outpatient clinic.
2. Blood (40ml) and urine samples for the Biobank of all the patients referred to the HFpEF outpatient clinic.
3. HFpEF patients included in the METC162032 study will be asked for extra blood analysis to isolate inflammatory cells (30ml). HFpEF patients included in the METC162032 study willl give a total of 70ml of blood.
4. 20 hypertensive control patients included in the METC162032 study will be asked for blood (40ml) and urine samples for the Biobank and extra blood analysis to isolate inflammatory cells and extracellulaire vesicles (40ml). Hypertensive controls will give a total of 80ml of blood.

Study population: All patients referred to the HFpEF outpatient clinic and 20 hypertensive controls.

Main study parameters/endpoints:

(1) Set up a cohort of HFpEF patients with a detailed clinical characterization of their phenotype.

(2) Set up a biobank, to analyse different biomarker profiles which will help to stratify HFpEF patients
(3) Investigate if patients without HFpEF, hypertensive controls that will be included in the “HFpEF-cohort perfusion and metabolism study”(NL57468.068.16/METC162032) have different biomarker profiles compared to the HFpEF patients.
(4) Isolate monocytes, neutrophils, T cells and platelets in HFpEF and hypertensive control patients included in the “HFpEF-cohort perfusion and metabolism study” (NL57468.068.16/METC162032) to understand better the pathophysiology, phenotype HFpEF patients and assess the differences with patients without HFpEF.
(5) Evaluate the changes in biomarker, urine and cellular expression (monocytes, neutrophils, T cells and platelets) after one year of all HFpEF patients included in the cohort and clinically followed up in out out-patient clinic.
(6) Evaluate whether our personalized, multidisciplinary treatment strategy improves quality of life and exercise tolerability and reduces hospitalizations.
(7) Increase awareness around this challenging syndrome.
(8) Evaluate platelet function by analysing extracellular vesicles in blood of hypertensive control patients. The function of these extracellular vesicles will be compared tin future projects to the one in HFpEF patients.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is not any risk associated with the participation in this study.

Doel van het onderzoek

Our goal is to build up a deep phenotyped HFpEF cohort, to be able to select the right patients for different HFpEF studies with the final goal of improving the understanding of the pathophysiology of HFpEF. The HFpEF cohort will allow us to understand the relationship between the different comorbidities and the clinical outcome.
Moreover, the HFpEF cohort will allow us to select the right patients to included in phase 2 and 3 medical trials.
We also want to analyse if the analysis of different blood, of urine biomarker profiles will help to stratify HFpEF patients. Moreover, we will include 20 control hypertensive patients as a control group to be able to analyse the difference in clinical parameters and biomarkers between HFpEF and hypertensive patients.

Onderzoeksopzet

Patients will be included until a number of 1000 is reached

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

There are no specific inclusion criteria for the patients referred to the HFpEF outpatient clinic. All patients above 18 years that have the ability to give the informed consent will be included in the cohort and blood and urine samples for the biobank will be obtained.

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:

- Inability to give informed consent or refusal to participate in the study
- Age <18 years

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8096
Ander register	METC AZM/MUMC : METC 18-057

Resultaten