

Heart Failure with Preserved Ejection Fraction HFpEF - a prospective cohort

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25965

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Heart Failure with Preserved Ejection Fraction

Sponsors and support

Primary sponsor: Investigator initiated

Source(s) of monetary or material Support: Investigator initiated

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

2. Set up a cohort of HFpEF patients with detailed clinical characterization of their phenotype.

3. Set up a biobank, to analyse different biomarker profiles which will help to stratify HFpEF patients
4. 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.
5. 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.
6. 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. 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 that in future projects will be compared to HFpEF patients.

Study description

Background summary

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, extracellular 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 will 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 extracellular 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-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 in 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.

Study 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 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.

Study design

Patients will be included until a number of 1000 is reached

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	17-10-2019
Application type:	First submission

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
NTR-new	NL8096
Other	METC AZM/MUMC : METC 18-057

Study results