Evaluation of Heart Failure with preserved Ejection Fraction and peripheral microvascular dysfunction

Published: 03-04-2019
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To identify differences in peripheral microvascular function in HFpEF patients compared to controls without HFpEF, corrected for important confounders of microvascular function

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

Summary

ID

NL-OMON55466

Source
ToetsingOnline

Brief title
HFpEF and peripheral microcirculation

Condition

- Other condition
- Heart failures

Synonym
Heart failure with preserved ejection fraction, heart failure with preserved pump function

Health condition

bloedvataandoeningen, verminderde functie van microcirculatie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Diastolic Heart Failure, Heart failure with preserved ejection fraction, Microcirculation, Microvascular dysfunction

Outcome measures

Primary outcome

The primary study parameter is peripheral microvascular function assessed by flicker-light induced retinal microvascular %-dilation measured with Dynamic Vessel Analyzer, corrected for the most important confounders of microvascular function.

Secondary outcome

- Difference in peripheral microvascular function assessed by heat-induced skin hyperaemia, finger capillary recruitment, or glycocalyx assessment in HFpEF patients compared to matched controls.
- Difference in macrovascular function assessed by carotid-femoral pulse wave velocity, intima-media thickness ratio, or ankle/arm-index in HFpEF patients compared to matched controls.
- Difference in physical activity assessed by the modified Champs questionnaire in HFpEF patients compared to matched controls.

Study description

Background summary

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. Microcirculation dysfunction is thought to play a central role in development of HFpEF, evidence of this concept is increasing. Moreover, it is unclear whether microvascular function differences lead to the observed higher prevalence of HFpEF in women.

Study objective

To identify differences in peripheral microvascular function in HFpEF patients compared to controls without HFpEF, corrected for important confounders of microvascular function

Study design

This is a case-control study. Peripheral microvascular and macrovascular assessments are performed within the Maastricht Study infrastructure and comply with previously approved Standard Operating Procedures (SOP*s). Clinical data resulted from clinical diagnostic tests performed during standard clinical care will be collected for characterization of the study population and for pooled analysis.

Study burden and risks

There is not any risk associated with the participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
HFpEF patients:
- HFpEF diagnosis based on ESC 2016 diagnostic criteria.
- Aged 60 years or older., Controls with diabetes mellitus:
- Diabets mellitus diagnosis based on World Health Organization 2006 criteria.
- Aged 60 years or older., Controls without DM:
- No diabets mellitus diagnosis based on World Health Organization 2006 criteria.
- Aged 60 years or older.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
HFpEF patients:
- Inability to give informed consent.
- Contraindications for pupil dilation by ocular drips, which is needed for the primary endpoint of this study assessed by flicker-light induced retinal vessel reactivity: a history of acute glaucoma, previous allergic reaction to ocular dilation drips. pregnancy or giving breastfeeding, current presence of intraocular oil or gas after retinal detachment.
- Contraindication for flicker-light induced retinal vessel reactivity assessment: history of photosensitive epilepsy.,

Controls with diabetes mellitus:
- A history of heart failure.

Controls without diabetes mellitus:
- A history of heart failure.

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):	25-04-2019
Enrollment:	1850
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23162
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68796.068.19
OMON	NL-OMON23162

Study results

Date completed: 30-10-2023

Actual enrolment: 2278

Summary results
Trial ended prematurely