Investigation of systemic microvascular dysfunction in heart failure with preserved ejection fraction in males and females

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HFpEF patients have impaired peripheral microvascular function compared to controls without HFpEF, with correction for important confounders of microvascular function.

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

Summary

ID

NL-OMON23162

Source
Nationaal Trial Register

Brief title
PROSE-HFpEF

Condition

- Heart failures

Health condition

Heart Failure with preserved Ejection Fraction (HFpEF)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch ziekenhuis Maastricht
Source(s) of monetary or material Support: Dutch Heart Foundation

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome
The primary endpoint of this study is the difference in peripheral microvascular function assessed by flicker-light-induced retinal arteriolar microvascular %-dilation (retinal arteriolar dilation) in patients with HFpEF compared to control individuals, corrected for the most important confounders of microvascular function and HFpEF.

Secondary outcome
- Other microvascular assessments that are similarly tested for differences between patients with HFpEF and control individuals included retinal, skin, and renal microvascular beds: flicker-light-induced retinal venular microvascular %-dilation, static retinal arteriolar and venular vessel diameters (calibres), skin flowmotion, skin heat-induced hyperaemia, and urine albumin-creatinin ratio.

- Additional analyses similarly performed include finger capillary recruitment, and sublingual glycocalyx assessment

- Difference in macrovascular function assessed by carotid-femoral pulse wave velocity, intima-media thickness ratio, or ankle/arm-index in HFpEF patients compared to control individuals, corrected for the most important confounders of microvascular function and HFpEF.

- Difference in physical activity assessed by the modified Champs questionnaire in HFpEF patients compared to control individuals, corrected for the most important confounders of microvascular function and HFpEF.

Study description

Background summary

About 142.000 individuals in the Netherlands have the diagnosis heart failure. About 50% of these people have heart failure with preserved ejection fraction (HFpEF). HFpEF is a complex syndrome with a high morbidity and mortality. The incidence of HFpEF has increased the past

decennium with 1% per year. The diversity in clinical phenotype and limited understanding of the underlying pathophysiology of HFpEF is one of the most important reasons why we have no effective therapy to date. The heterogeneity of HFpEF could potentially be the puzzle in which we find a therapy. It is therefore important to extensively map HFpEF patients to clarify which elements are deflected and how these elements interact with each other. Based on multiple studies the current hypothesis is that microvascular dysfunction plays a key role in the development of HFpEF, the evidence in HFpEF patients is increasing but still limited. With this study we intend to further clarify the peripheral microvascular function in HFpEF patients in a non-invasive manner. Results of this study can give additional information regarding phenotypes of HFpEF and potentially offer a new therapeutical window.

Study objective

HFpEF patients have impaired peripheral microvascular function compared to controls without HFpEF, with correction for important confounders of microvascular function.

Study design

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Intervention
Not applicable. Non-interventional observational study.

Contacts

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Eligibility criteria

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

Inclusion criteria

Patients with HFpEF

Patients with HFpEF were eligible to participate in this study based on the following inclusion criteria:

- HFpEF diagnosis based on the European Society of Cardiology (ESC) heart failure 2016 guidelines' diagnostic criteria.

- Aged 60 years or older.

Controls

Data of controls already participating in the Maastricht Study was used. All controls signed informed consent prior to using their data for the current study.

Controls were selected based on the following inclusion criteria:

- Aged 60 years or older

- Data available of primary endpoint

Exclusion criteria

Exclusion criteria for participation in patients with HFpEF:

- 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 were excluded based on the following criteria:

- A history of HF at baseline or HF during one-year follow-up after baseline.

- Suspected severe cardiac valve disease or decreased left ventricular ejection fraction during baseline echocardiography. Or if no echocardiography was performed.

- Inclusion as HFpEF patient in the current study.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Screening

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-04-2019
Enrollment:	1850
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data can be made available to other researchers upon reasonable request to the coordinating researcher. Only pseudonymized data is shared from participants who provided explicit consent for data sharing, with the purpose to increase knowledge of HFpEF or microvascular dysfunction. Data sharing policies of the Maastricht Study apply to data of control individuals.

Ethics review

Approved WMO

Date:	03-04-2019
Application type:	First submission
Review commission:	METC Academisch Ziekenhuis Maastricht / Universiteit

Maastricht

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Study registrations

Followed up by the following (possibly more current) registration

ID: 55466
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7655
CCMO	NL68796.068.19
OMON	NL-OMON55466

Study results