Early detection of diastolic dysfunction and heart failure with preserved ejection fraction

Published: 26-06-2019
Last updated: 19-03-2025

Which markers and which vascular calcifications can be used as diagnostic markers in the dectecion of heart failure with preserved ejection fraction and diastolic dysfunction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON55962

Source
ToetsingOnline

Brief title
EARLY-HFPEF

Condition

- Congenital cardiac disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Vascular disorders NEC

Synonym
Heart failure with preserved ejection fraction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: CVON-subsidie: early-HFpEF project; ZonMW

NWO-Vidi grant (91 71 8304)

Intervention

Keyword: Diastolic dysfunction, Heart failure, Preserved ejection fraction, Type 2 diabetes

Outcome measures

Primary outcome

Heart failure with preserved ejectionf fraction based on echocardiographic

measurements, clinical measurements and biomarkers.

Secondary outcome

-

Study description

Background summary

Approximately 70% of people with type 2 diabetes develop a specific form of heart failure, namely heart failure with preserved ejection fraction. This type of heart failure results in relaxation problems of the heart, in which the blood cannot be pumped to the heart in a proper way.
Heart failure with preserved ejection fraction is hard to detect. Differences in size, shape and function of the heart are found in people with type 2 diabetes. The detection of these changes can help to diagnose these people with a high risk of heart failure with preserved ejection fraction, so we can treat these people properly.

Study objective

Which markers and which vascular calcifications can be used as diagnostic markers in the dectecion of heart failure with preserved ejection fraction and diastolic dysfunction.

Study design

Cross-sectional observational study. 250 participants from the Early-HFpEF study will be invited after three years for a follow-up study visit.

Study burden and risks

The duration of the visit will last 2.5 - 3 hours and will take place in two seperate study visits;
removal of the electrodes of the echocardiography can hurt a little; a chance of bruising as a result of the venapuncture.

The CT-scan will not cause any pain in the study participants and has no direct side effects. However, the X-rays can have long-term risks. It is known that there is an increased risk of developing cancer when exposed to X-rays. The dose in this study is very low; therefore the risk is negligibly small.

The additional measurements for the microvascular endothelial function, which will be executed in a subgroup of 150 participants, can give some minor erythema, edema or redness of the skin, due to the application of a vasoactive solution on the skin.

Contacts

Public
Vrije Universiteit Medisch Centrum

de Boelelaan 1089a
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

de Boelelaan 1089a
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Males and females aged 50-75 years;
duration of T2DM of at least 1 year (defined on the basis of previous diagnosis and/or treatment with hypoglycaemic agents);
with informed consent to be contacted for future research;
able to provide a written consent form.

Exclusion criteria

1. Advanced diabetes complications (like proliferative retinopathy, disabling polyneuropathy, or stages IV-V diabetic nephropathy). 2. Cardiac comorbidity: a) Valvular heart disease requiring surgery or intervention, or within 3 months after valvular surgery or intervention. b) Hypertrophic obstructive cardiomyopathy. c) Acute myocarditis, sarcoidosis, amyloidosis, Takotsubo cardiomyopathy. d) Post-heart transplant cardiomyopathy. e) Chronic HFrEF (a LV EF of < 50% assessed within 12 months prior to randomization). f) Clinical diagnosis of HFpEF. g) Tachycardia-induced cardiomyopathy and/or uncontrolled tachyarrhythmia. h) Acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction [NSTEMI]or ST elevation myocardial infarction [STEMI]) or coronary revascularization (coronary artery bypass grafting [CABG] or percutaneous coronary intervention [PCI]) within 60 days prior to the enrolment, or indication for coronary revascularization at time of enrolment. i) Symptomatic carotid stenosis, transient ischemic attack (TIA) or stroke within 60 days prior to randomization. j) Congenital heart disease. k) Active endocarditis or constrictive pericarditis. 3. Non-cardiac comorbidity a) Estimated glomerular filtration rate (eGFR) calculated based on the Modification of Diet in Renal Disease (MDRD) equation <15 mL/min/1.73 m2 or chronic dialysis. b) Severe hepatic insufficiency. c) Malignancy or other non-cardiac condition limiting life expectancy to < 3 years. d) e) Mental or legal incapacitation and is unable to provide informed consent. 4. Participation in the LIDDIA or intervention part of the PRIORITY study. Additionally, participants implanted with internal cardiac pacemakers will be excluded from participation to the additional LASCA measurements.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2019
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO Date:	26-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 21126
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64774.029.18
OMON	NL-OMON21126