A dynamic, multiple-biomarker approach aiming for individualized treatment of heart failure with preserved ejection fraction

Published: 02-09-2022
Last updated: 13-06-2024

Primary Objective:- To investigate the association between temporal evolutions of blood biomarkers and clinical adverse events, in order to produce a dynamic, individual, and accurate prediction model for patients with HFpEFSecondary Objective(s):-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON51533

Source
ToetsingOnline

Brief title
ADAPT-HFpEF

Condition

- Heart failures

Synonym
Heart failure; HFpEF

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum

Source(s) of monetary or material Support: Jaap Schouten Foundation

Intervention

Keyword: Biomarkers, Heart failure, HFpEF, Repeated measurements

Outcome measures

Primary outcome

The primary endpoint is a combined endpoint of urgent visit resulting in intravenous therapy for HF, hospital readmission for acute or worsened HF, and cardiovascular death.

Secondary outcome

The secondary endpoints are:

- the separate components of the combined primary endpoint; urgent visit resulting in intravenous therapy for heart failure, hospital readmission for acute or worsened HF, and cardiovascular death.

- The combined endpoint urgent visit resulting in intravenous therapy for HF, hospital readmission for acute or worsened HF, and all-cause death.

- All-cause death

- Myocardial infarction (fatal and non-fatal), stroke (fatal and non-fatal), percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG)

- Cardiovascular disease (includes all of the above, except all-cause death)

Study description

Background summary

Heart failure with preserved ejection fraction (HFpEF) is a dynamic, heterogeneous clinical syndrome. Its prognosis is just as ominous as that of heart failure with reduced ejection fraction (HFrEF), with approx. 50% mortality in the first five years after diagnosis. There is much to gain in the assessment of individual prognosis of HFpEF patients, in order to contribute to better timing of additional treatment and therefore to a more favourable disease course. Repeated blood biomarker measurements may detect unfavourable changes before they become clinically apparent, and could herewith contribute to improved risk assesment. Moreover, blood biomarkers could be used to derive HFpEF sub-phenotypes with differences in clinical characteristics and prognosis. Such protein-based sub-phenotyping could help us gain further insights into the underlying pathophysiological mechanisms of HFpEF.

Study objective

Primary Objective:
- To investigate the association between temporal evolutions of blood biomarkers and clinical adverse events, in order to produce a dynamic, individual, and accurate prediction model for patients with HFpEF

Secondary Objective(s):
- To describe temporal evolution of biomarkers in patients that experience the primary endpoint and in patients that do not
- To uncover HFpEF sub-phenotypes based on baseline levels and temporal evolutions of blood biomarkers
- To investigate differences in clinical characteristics and prognosis of these HFpEF sub-phenotypes.
- To obtain insights into underlying pathophysiological mechanisms of HFpEF, based on these sub-phenotypes.

Study design

This is a prospective, observational multi-center cohort study. It will be conducted at the Cardiology departments of the Erasmus Medical Center (EMC) as well as five peripheral hospitals. A total of 200 HFpEF patients will be included in the study through the outpatient clinics. The follow-up period is a minimum of 2 years and a maximum of 3.5 years. Clinical data will be collected at baseline, and blood samples will be repeatedly collected, at baseline followed by 6-month intervals. Protein measurements will be performed at the end of follow-up.

Study burden and risks

The regular treatment of the patients will not be interfered with as this is an observational study. The main burden of this study consists of 5 to 8 visits to the outpatient clinic during 2 to 3.5 years of follow-up. However, by combining

the study visits with planned outpatient clinic visits as much as possible, extra visits will be kept to a minimum. Procedures during the extra study visits include venipuncture and also baseline echocardiography. Risks associated with these procedures are generally considered negligible. There are no individual benefits of participation, besides the contribution to obtaining scientific knowledge for the future.

Contacts

Public
Selecteer

's-Gravendijkwal 230
Rotterdam 3015CE
NL
Scientific
Selecteer

's-Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age of 18 years or older
AND
- Capable of understanding and signing informed consent
AND

- A diagnosis of HFpEF according to the HFA-PEFF diagnostic algorithm of the ESC,
OR
- a high (90%) probability of HFpEF according to the H2FPEF score, i.e. a score of 6 or higher

Exclusion criteria

-History of LVEF <=40%
-Scheduled for surgery or intervention for both coronary and non-coronary indication within 6 months of inclusion
-Impaired renal function, defined as eGFR < 20 mL/min/1.73 m2 (CKD-EPI) or requiring dialysis at the time of screening
-Acute or chronic liver disease, defined by serum levels of transaminases or alkaline phosphatase more than three times the upper limit of normal at screening
-COPD Gold stage IV
-Congenital heart disease
-Pregnancy
-Coexistent condition with life expectancy of <1 year
-Unlikely to appear at all scheduled follow-up visits
-Linguistic barrier

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):	25-11-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-06-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL80596.078.22