Value of Intensive Phenotyping in Heart Failure with preserved ejection fraction

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To assess the risk profile associated with the combined endpoint of all-cause mortality and HF hospitalizations in HF patients with LVEF >0.40.

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

Summary

ID

NL-OMON50839

Source
ToetsingOnline

Brief title
VIP-HF2 registry

Condition

- Heart failures

Synonym
Diastolic heart failure; heart failure with preserved ejection fraction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Heart failure hospitalization, Heart failure with preserved ejection fraction

(HFpEF), Mortality, Phenotyping

Outcome measures

Primary outcome

Incidence of the combined endpoint of all-cause mortality and heart faillure hospitalizations.

Secondary outcome

1. To assess the risk profile associated with incident atrial fibrillation (AF) in patients without baseline or history of AF.

2. To assess the risk profile associated with HF hospitalizations, all-cause mortality, cardiovascular mortality and sudden death separately.

3. To assess the risk profile associated with cardiac amyloid deposition.

Study description

Background summary

Heart failure (HF) with a left ventricular ejection fraction (LVEF) >0.40 is a large medical problem, for which no drug or device has a recommendation in current HF guidelines. The prevalence of mortality and HF hospitalizations in HF with LVEF >0.40 is high, but the identification of predictors for increased risk of mortality and HF hospitalizations in this patient category remains difficult. The hypothesis of this study is that the risk of all-cause mortality and HF hospitalizations can be measured by clinical factors, imaging parameters and circulating biomarkers, and that these factors can be used in a risk profile.

Study objective

To assess the risk profile associated with the combined endpoint of all-cause mortality and HF hospitalizations in HF patients with LVEF >0.40.

Study design

Single-center, prospective, non-randomized, observational study. Total duration

is 5 years.

Study burden and risks

The present study may render important insights into the incidence of all-cause mortality and heart failure hospitalizations in patients with HFpEF. Eventually, this may lead to improved risk stratification, therapeutic choices and hence patient-tailored therapy. At present no drug or device therapy has been proven beneficial in patients with HFpEF. Blood sampling occurs during vena punctures performed for usual care. Risks of a vena puncture are very slight and include excessive bleeding, fainting or feeling light-headed, hematoma, local infection. Obtaining a blood sample from some people may be more difficult than from others. The usage of positron emitting isotopes in the 99m technetium scan translates to an exposure to ionizing radiation. Because of the potential hazards of radiation exposure, guidelines for the exposure of healthy volunteers are laid down in *Besluit stralingsbescherming, artikel 60, staatblad 2001, 397* in accordance with the guidelines of the International Commission on Radiological Protection (ICRP). The radiation dose of 99mTc-HDP is 0.0057 mSv/MBq for adults. Patients will receive a total dose of 500 MBq IV, which translates to a total radiation dose of ± 2.9 mSv for the 99mTc-HDP scan. The radiation of a low dose CT is approximately 0.5 mSv, which totals to a dose of 3.4 mSv combined with the 99mTc-HDP scan. This complies with category IIb, ICRP 62. The radation dose is calculated by our local clinical physicist. There are no other study-related procedures required. There are no other study-related procedures required.

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

Clinical criteria: 1. Age >18 years 2. Written informed consent 3. HF with moderate to severe symptoms NYHA II or III 4. Hospitalization or emergency room visit for HF or symptom relief with diuretics 5. Sinus rhythm or AF, Echocardiographic criteria: 1. LVEF >40% 2. Left atrial size (volume >=29 mL/m2 or LA parasternal diameter >=45 or left ventricular hypertrophy (septal thickness or posterior wall thickness >=11 mm) of left ventricular diastolic dysfunction (E/e* >=13 or mean e* septal and lateral wall <9 cm/s)., Biomarker criteria: 1. BNP >31ng/L or NT-pro-BNP>125ng/L if sinus rhythm 2. BNP >75ng/L or NT-pro-BNP>300ng/L if atrial fibrillation

Exclusion criteria

1. Patients unwilling or unable to sign informed consent 2. Patients with a pacemaker or ICD 3. Indication for ICD therapy according to the European Society of Cardiology (ESC) guidelines 4. Life expectancy of less than one year 5. Significant coronary artery disease or myocardial infarction < 3 months 6. Complex congenital heart disease 7. Pregnancy

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01989299
CCMO	NL75981.042.21