Serial Biomarker meaSurements and new echocardiographic techniques in chronic Heart Failure patients result in Tailored prediction of prognosis

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Primary Objectives: - To investigate whether disease progression in individual patients with CHF can be accurately assessed by serial measurements of disease-related (novel) biomarkers.- To investigate whether dynamic biomarker patterns as...

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

Summary

ID

NL-OMON44136

Source
ToetsingOnline

Brief title
Bio-SHiFT

Condition

- Heart failures

Synonym
heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, Echocardiography, Epidemiology, Heart failure

Outcome measures

Primary outcome

The primary endpoint is the composite of cardiovascular death, cardiac transplantation, left ventricular assist device implantation, and re-hospitalization for the management of acute or worsened heart failure.

Secondary outcome

Secondary endpoints include:

- The individual components of the primary endpoint, i.e. cardiovascular death, cardiac transplantation, left ventricular assist device implantation and re-hospitalization for acute or worsened heart failure
- 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)
- All-cause mortality

Study description

Background summary

Diagnosis of decompensation in patients with chronic heart failure (CHF) and initiation of additional treatment is currently only possible when symptoms have become manifest. Consequently, treatment also can only start at this stage. As such, there is an urgent need for reliable non-invasive measures of

pre-symptomatic decline of cardiac function.

HF results from a complex interplay among neurohormonal, inflammatory and biochemical changes. Biomarkers have the potential to monitor subtle changes in the heart that reflect and possibly predict adverse changes before they become clinically apparent. Use of serial biomarker measurements (as opposed to a single measurement at baseline) may provide information on individual patterns of change and may therefore contribute to personalized medicine. In the current study we will investigate whether such serial biomarker measurements can be used to improve prognostication in chronic heart failure patients.

As a substudy, we will investigate whether 2 new echocardiographic techniques improve prognostication in chronic heart failure patients. Until now, the state-of-the-art echocardiographic technique used in chronic heart failure patients in Tissue Doppler. However, this technique has limitations such as the poor signal-to-noise ratio, and therefore, new alternatives are needed. In th current study, we will investigate which echocardiographic technique is best suited to visualize cardiac function and we will correlate the prognostic value of the echocardiographic techniques with serial biomarker measurements.

Should the serial biomarker measurements and the new echocardiographic techniques prove to be useful in prognostication, then this would contribute to individualized medicine in patients with heart failure. Treatment would become possible at an earlier stage and the progression and the effect of treatment could be monitored more closely. This could contribute to improved clinical outcomes and improved quality of life in patients with heart failure.

Study objective

Primary Objectives:
- To investigate whether disease progression in individual patients with CHF can be accurately assessed by serial measurements of disease-related (novel) biomarkers.
- To investigate whether dynamic biomarker patterns as determined during serial measurements provide additional prognostic value in individual patients with CHF when compared to the static risk models that include a single biomarker measurement at baseline. In other words, to examine how the initial assessment of prognosis is influenced by the results of repeated biomarker measurements over a longer period of time.
- To compare serial biomarker patterns in chronic HF patients with diminished and normal ejection fraction and thereby further elucidate etiologic mechanisms.

Objectives of the echocardiographic substudy:
- To compare Speckle tracking with TDI in CHF patients; relate measurements by Speckle tracking and TDI to cardiovascular outcome
- To assess the feasibility of applying 3D-echocardiography in a CHF

population; compare 2D- with real-time 3D-echocardiography in CHF patients; relate measurements by 2D- and 3D-echocardiography to outcome
- To correlate serial echocardiographic measurements with serial biomarker values.

Study design

This is a prospective, observational, multi-center, cohort study.

Study burden and risks

The main burden of this study consists of extra visits to the outpatient clinic (twice per year) and of extra venipunctures (a total of 5 times) during a maximum period of 30 months.

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

1. Men and women, aged 18 years or older, capable of understanding and signing informed consent
2. Diagnosis of chronic heart failure, systolic and diastolic, according to the guidelines of the European Society of Cardiology (ESC)

Exclusion criteria

1. Heart failure secondary to circulatory high output conditions
2. Scheduled for surgery or intervention for both coronary and non-coronary indication within 6 months of inclusion
3. Severe renal failure for which dialysis is needed
4. Coexistent condition with life expectancy * 1 year
5. Unlikely to appear at all scheduled follow-up visits
6. Known moderate or severe liver disease
7. COPD Gold stage IV
8. Congenital heart disease
9. Linguistic barrier

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-12-2016
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	NL34532.078.10