Hartfalen biomarker studie (TRIUMPH).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27910

Source
NTR

Brief title
TRanslational Initiative on Unique and novel strategies for Management of Patients with Heart failure (TRIUMPH)

Health condition

heart failure; acute and chronic; candidate biomarkers; clinical validation; tailored therapy; disease progression; therapeutic efficacy. hartfalen; acuut en chronisch; kandidaat biomarkers; klinische validatie; op het individu toegespitste therapie; ziekte progressie; therapeutische effectiviteit.

Sponsors and support

Primary sponsor: Center for Translational Molecular Medicine
Source(s) of monetary or material Support: Center for Translation Molecular Medicine; Netherlands Heart Foundation; Erasmus MC; UMCG.

Intervention

Outcome measures

Primary outcome

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

failure.

Secondary outcome

The secondary endpoints include:

1. Individual components of the primary endpoint, i.e. cardiovascular death, left ventricular assist device implantation, heart transplantation and re-hospitalization for acute heart failure;

2. Cardiovascular death, left ventricular assist device implantation, heart transplantation, re-admission to hospital for acute heart failure, or non-fatal myocardial infarction;

3. Cardiovascular death, left ventricular assist device implantation, heart transplantation, re-admission to hospital for acute heart failure, non-fatal myocardial infarction, or non-fatal stroke.
4. Cardiovascular death, left ventricular assist device implantation, heart transplantation, re-admission to hospital for acute heart failure, non-fatal myocardial infarction, non-fatal stroke, or coronary revascularization.
5. Death (any cause) or left ventricular assist device implantation, heart transplantation, re-admission to hospital for acute heart failure;

6. Number of appropriate ICD shocks;

7. Estimated glomerular filtration rate as measured with the simplified MDRD formula;

8. Quality of life by Kansas City Cardiomyopthy Questionnaire, EQ-5D;

9. Depressive symptoms by Hospital Anxiety and Depression scal;

10. Symptoms by symptom occurence and burden questionnaire.

Study description

Background summary

Summary:

Until now, different biomarkers for heart failure (HF) show only modest clinical usefulness regarding improvement of earlier diagnosis, subsequent risk prediction and stratification, guiding HF therapy, and, finally, in some cases, serving as a target for therapy. Given the imprecision of current biomarkers, the search for new biomarkers is a clinically important objective, especially given the limited community resources.

The TRIUMPH clinical cohort aims to identify and validate potentially clinically important

biomarkers. These novel biomarkers need to be implemented in the clinical management of acute (and chronic) HF patients to monitor disease progression and therapeutic efficacy, as well as to sub-diagnose and guide tailored therapy. For this purpose, a novel dedicated cohort of patients with acute heart failure will be generated which will be designed to allow assessment of the value of the selected biomarkers.

This is a prospective and observational study performed in approximately 10 to15 centres in The Netherlands. The Erasmus Medical Center Rotterdam and University Medical Center Groningen will act as the initiating and coordinating centres. A patient cohort consisting of at least 1000 patients hospitalized for acute heart failure (i.e. new presentation of heart failure or exacerbation of known, chronic heart failure) will be recruited. From each HF patient blood samples will be taken and morning urine will be obtained at each of the follow-up visits (8 times during 9-12 months). A detailed protocol will be developed for blood and urine collection, blood and urine sample handling and (long-term) storage (-80 °C), so that the handling and storage of the blood and urine samples will be comparable among the participating centres. Assessment of quality of life and a sub study on echocardiography will be part of the TRIUMPH.

Study objective

The TRIUMPH clinical cohort aims to identify and validate potentially clinically important biomarkers. These novel biomarkers need to be implemented in the clinical management of acute (and chronic) heart failure patients to monitor disease progression and therapeutic efficacy, as well as to sub-diagnose and guide tailored therapy.

Study design

1. Primary and secondary outcome are assessed during 9-12 months follow up;

2. Quality of life, depressive symptoms and symptoms are assessed at discharge from the hospital and at the end of the study period (9-12 months).

Intervention

None.

Contacts

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Eligibility criteria

Inclusion criteria

Patients to be included must meet the following criteria:

1. Men and women, aged 18 years or older, capable of understanding and signing informed consent;

2. Hospital admission with a diagnosis of acute heart failure (i.e. new presentation of heart failure or exacerbation of known, chronic heart failure);

3. Natriuretic peptide (BNP or NT-proBNP) levels ¡Ý 3 x ULN;

4. Treated with intravenous diuretics during the hospitalization;

5. All patients have to provide written informed consent;

6. Evidence of sustained systolic or diastolic left ventricular dysfunction on echocardiography (recorded within the last year or during current hospitalization).

Exclusion criteria

Patients will be excluded from this study for any of the following reasons:

1. Heart failure precipitated by a non-cardiac condition (e.g. severe anemia, pulmonary embolism, thyrotoxicosis, etc);

2. The clinical syndrome of heart failure caused by severe valvular dysfunction or severe cardiac arrhythmias without evidence of sustained systolic or diastolic dysfunction;

3. Acute heart failure caused by an acute ST-segment elevation myocardial infarction requiring reperfusion therapy;

4. Acute heart failure caused by an acute coronary syndrome without evidence of sustained systolic or diastolic dysfunction;

5. A planned coronary intervention (PCI and/or CABG);

6. Patients with end-stage heart failure who are on the waiting list for cardiac transplantation;

7. End-stage chronic kidney disease requiring dialysis;

8. Non-cardiac condition associated with a life-expectancy <1 year, or otherwise unlikely to appear at all scheduled follow-up visits;

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2009
Enrollment:	1000
Type:	Actual

Ethics review

Positive opinion

Date:	02-07-2009
Application type:	First submission

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
NTR-new	NL1783
NTR-old	NTR1893
Other	METC Rotterdam; CTMM : 2009/128; workpackage 6
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A