Hartfalen biomarker studie (TRIUMPH).

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27910

Bron
NTR

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

Aandoening

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.

Ondersteuning

Primaire sponsor: Center for Translational Molecular Medicine
Overige ondersteuning: Center for Translation Molecular Medicine; Netherlands Heart Foundation; Erasmus MC; UMCG.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

None.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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;

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2009
Aantal proefpersonen:	1000
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-07-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1783
NTR-old	NTR1893

Register	ID
Ander register	METC Rotterdam; CTMM : 2009/128; workpackage 6
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A