Prognostic models and biomarkers in patients with acute decompensated heart failure admitted to ward

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

Summary

ID

NL-OMON46619

Source
ToetsingOnline

Brief title
HF on Ward

Condition

- Heart failures

Synonym
acute decompensated heart failure, acute heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Rijksdienst voor ondernemend Nederland

Intervention

Keyword: acute decompensated heart failure, biomarkers, prognostic models, risk score

Outcome measures

Primary outcome

The main study parameters will be the ELAN-HF score, biomarker levels and clinical data that is collected during study inclusion. The main study endpoints are all-cause mortality and a composite of all-cause mortality and/or first readmission for cardiovascular reasons within 6 months after discharge.

Secondary outcome

Assess the associations between biomarker levels in patients admitted with ADHF and:

- cause-specific mortality 6 months after discharge.

- recurrent hospitalizations.

- QoL outcomes early after discharge and 6 months after discharge.

Develop a prognostic model that predicts QoL outcomes for patients that are admitted with acutely decompensated heart failure, based on serial measurements of a panel of biomarkers and clinical variables contained in electronic health records.

Assess prognostic value of features extracted from continuous PPG and accelerometer data from the Elan device in patients that are discharged after they have been treated for ADHF. Assess agreement between a Hemodynamics model and the assessment of the degree of decompensation by the cardiologist.

Study description

Background summary

Heart Failure (HF) accounts for 1-3% of all US and European hospital admissions. Patients admitted with acute decompensated HF (ADHF) have poor short- and long-term prognosis, after discharge * 20% of patients are readmitted within 30 days and up to 50% by 6 months. A reduction in HF readmissions simultaneously improves the quality of care and reduces costs. To reduce HF readmission rates a comprehensive characterization of predictors of readmission in patients with HF is imperative. Multivariable risk scores can predict risk for adverse events such as readmission or mortality in patients admitted with ADHF. High risk patients can be targeted for intervention or indicate incomplete treatment in hospital. The ELAN-HF score is a novel, simple and yet robust discharge risk score developed by Salah et. al that incorporates natriuretic peptide levels in addition to known risk markers to predict adverse events. Next to natriuretic peptide levels, other biomarkers have emerged that allow prognostication of patients admitted with ADHF. Recent studies have shown that combining multiple biomarkers in a multimarker panel, substantially improves prediction of adverse events beyond current metrics.

Study objective

Since the ELAN-HF score has only been externally validated in one cohort, the primary objective of this study is to perform an external validation of the ELAN-HF score in a cohort of patients admitted with ADHF at the Catharina Hospital. A second primary objective is to serially measure a multimarker panel in this cohort and combine these measurements with clinical data from multiple sources (e.g. prescribed medication, medical history, physiological measurements etc.) to capture the heterogeneous nature of HF in a novel discharge risk score.

Study design

This study is a prospective, non-randomized, observational, single-center cohort study.

Study burden and risks

There are minimal risks associated with participation in this study, most measurements performed during this study are part of routine care. The additional burden is presented in the form of extra vials of blood that need to be withdrawn on admission, discharge and one week of discharge, attachment of a watch that registers PPG signals (in a subgroup of patients), and three moments

in time where a questionnaire has to be filled in.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Undergo treatment for ADHF.
Aged 18 or above and mentally competent.
Capable of understanding the Dutch language.

Exclusion criteria

Patients where follow-up is not possible (e.g. in-hospital mortality or follow-up not taking

place at the Catharina Hospital).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-01-2019
Enrollment:	278
Type:	Actual

Ethics review

Approved WMO

Date:	03-08-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27799
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65323.100.18
OMON	NL-OMON27799