Can NT-proBNP guided therapy during hospital admission for acutely decompensated heart failure reduce mortality and readmissions?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21346

Source
Nationaal Trial Register

Brief title
PRIMA II study

Health condition

Acutely decompensated heart failure
Acute heart failure

Acuut hartfalen
Acuut gedecompenseerd hartfalen

Sponsors and support

Primary sponsor: Academical Medical Center - University of Amsterdam
Source(s) of monetary or material Support: The Dutch Heart Foundation
Roche Diagnostics BV

Intervention

Outcome measures

Primary outcome

1. Readmissions and mortality in the first 180 days;

2. The number of days alive out of hospital in the first 180 days.

Secondary outcome

1. Readmissions in the first 180 days;

2. Mortality in the first 180 days;

3. Cost effectiveness in terms of hospitalization days in the first 180 days;

4. Readmissions and mortality in the first 90 days.

Study description

Background summary

Guiding therapy of heart failure (HF) by an objective measure like NT-proBNP has received intense attention. The gain that is made by this form of guidance is modest when applied to chronic heart failure (CHF) patients. Recent post discharge data from our own group does show that NT-proBNP guidance can detect important short-term changes. Studies have also shown that NT-proBNP discharge value and a >30% NT-proBNP reduction during admission are statistically significant predictors of readmissions and mortality. These data suggest a role for such NT-proBNP guidance, rather in an acute than in a chronic setting. Acute admission for HF occurs frequent: in 2004, there were almost 25,000 hospital admissions in the Netherlands. Particularly worrisome is the high percentage of readmissions which reaches 30 to 60% within 6 months, importantly increasing the economic burden of this disease. In short, in-hospital care for acutely decompensated heart failure may be improved by NT-proBNP guidance to reduce the number of readmissions.

The primary objective of the present multicenter randomized controlled trial is to demonstrate that NT-proBNP guidance during in-hospital treatment for acutely decompensated heart failure (to strive for >30% reduction) reduces readmissions and mortality and increases the number of days alive out of hospital in the first 180 days compared to therapy guided by standard clinical judgment. Morbidity and mortality is measured in terms of days alive outside the hospital within the follow-up period of 180 days.

Study objective

NT-proBNP guidance during in-hospital treatment of acutely decompensated heart failure (to strive for >30% reduction) reduces readmissions and mortality and increases the number of days alive out of hospital in the first 180 days.

Study design

Endpoint assessment (readmission or death) will take place at 4 timepoints after discharge: 1 week, 1 month, 3 months and 6 months after discharge.

Intervention

1. NT-proBNP guided therapy;

2. Conventional therapy.

When clinical stability is achieved, the patient is randomized in either the NT-proBNP-titrated group or the conventional therapy group. In the NT-proBNP-titrated group a NT-proBNP reduction of > 30% before discharge is pursued. When patients do not reach the >30% NT-proBNP reduction, they follow a predefined algorithm before discharge to improve the number of patients discharged with >30% reduction in NT-proBNP levels. Hence, duration of admission can be prolonged with a maximum of 2-4 days. The NT-proBNP levels of patients in the conventional treatment group will be measured but not revealed to patients, physicians or nurses. Conventional treatment encompasses the recommended therapy depicted in the current guidelines for acute heartfailure.

Contacts

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Eligibility criteria

Inclusion criteria

1. Hospital admission because of clinically validated acutely decompensated heart failure. A clinical diagnosis of HF is made on the basis of a HF-score of 2 points or higher;

2.Elevated NT-proBNP levels ≥1700 ng/L (≥200 pmol/L) on hospital admission;

3. Written informed consent to participate in this study prior to any study procedures.

Exclusion criteria

1. Severe Chronic Obstructive Pulmonary Disease (COPD) with FEV<1l/min;

2. Pulmonary embolism within 1 month prior to admission and pulmonary hypertension not caused by left ventricle dysfunction (LVD);

3. Patients undergoing Continue Ambulant Peritoneal Dialysis (CAPD)/ Haemodialysis patients;

4. Patients with planned Coronary Artery Bypass Grafting (CABG), Percutaneous Coronary Intervention (PCI), Cardiac Resynchronization Therapy (CRT) and/or valvular surgery before admission (until one day before admission);

5. Patients with planned Coronary Artery Bypass Grafting (CABG), Percutaneous Coronary Intervention (PCI), Cardiac Resynchronization Therapy (CRT) and/or valvular surgery during admission until the moment of randomization;

6. Patient with a history of ST-segment-Elevated Myocardial Infarction (STEMI), CABG, PCI, CRT and/or valvular surgery within 1 month prior to admission;

7. Signed informed consent for any current interventional study;

8. Presence of severe non-cardiac related life-threatening disease before inclusion with an expected survival of less than 6 months after inclusion;

9. Mental of physical status not allowing written informed consent;

10. Unwillingness to give informed consent;

11. Circumstances that prevent follow-up (no permanent home address, transient, etc.).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	08-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44072
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3128
NTR-old	NTR3279
CCMO	NL36873.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44072

Study results

Summary results
N/A