Multi-center, randomized clinical trial to study the impact of in-hospital guidance for acutely decompensated heart failure treatment by predefined NT-proBNP targets (>30% reduction in NT-proBNP during admission) on the reduction of readmission rates and mortality

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Ethical review	-
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON44072

Source
ToetsingOnline

Brief title
Prima II

Condition

- Heart failures

Synonym
acutely decompensated heart failure, congestive heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NHS,Roche Diagnostics B.V.

Intervention

Keyword: acutely heart failure, NT-proBNP

Outcome measures

Primary outcome

The differences between the group which received the conventional therapie and

the intervention group, treated according to NT-proBNP levels in readmission

and mortalitly in the first 180 days.

Secondary outcome

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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.

Study objective

The primary objective of the present study 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. Endpoint events will be evaluated on an intention-to treat basis.

Secondary objectives of the present study are:
1. To demonstrate within and between group effects of NT-proBNP titrated therapy on secondary outcome measures such as final NT-proBNP levels.
2. To demonstrate NT-proBNP titrated heart failure therapy is cost-effective in terms of hospitalization days in the first 180 days compared to conventional clinically guided HF-therapy.
3. To demonstrate which of the proposed interventions to achieve >30% reduction in NT-proBNP are relevant to reduce readmission and mortality in the first 180 days.
4. To demonstrate that NT-proBNP guidance during in-hospital treatment for acutely decompensated heart failure (to strive for >30% reduction) reduces readmissions and mortality in the first 90 days compared to therapy guided by standard clinical judgment.
5. To assess whether primary and secondary outcome measures are exceedingly prevalent in patients with elevated NT-proBNP levels that are not responsive to pharmacological intervention.
6. To assess whether there is a significant difference in quality of life between the groups treated with NT-proBNP titrated therapy or conventional clinically-guided therapy.

Study design

Multi-center, randomized clinical intervention trial

Intervention

Of patients who enter the study baseline NT-proBNP will be measured within 24 hours. Consenting patients are randomly assigned to one of the following treatment strategies:
A. NT-proBNP guided treatment
B. Conventional clinically guided treatment

All patients will receive treatment for at least 3 days until they are

clinically stable. The randomization will take place during hospital admission from day three or whenever the patient is clinically stable. Patients will be included in a randomized controlled trial of NT-proBNP-titrated therapy (group A) versus standard clinically guided therapy (group B).

In the NT-proBNP-titrated group A, NT-proBNP-levels will be reported to the treating physician. The first NT-proBNP is measured within 24 hours after admission. After the initial treatment and randomization, when the patient is clinically stable, the NT-proBNP is measured again. Based on this NT-proBNP measurement the discharge and follow-up of the patient is planned if the patient meets both requirements: clinically stability and a NT-proBNP reduction of >30%.

The NT-proBNP levels of patients in the clinically guided group B will be measured but not revealed to patients, physicians or nurses. The first NT-proBNP is measured within 24 hours after admission. After the initial treatment and randomization, when the patient is clinically stable, the NT-proBNP is measured (blind). If the patient is indeed clinically stable; the physician should plan and organize the discharge and follow-up of the patient.

Study burden and risks

- The possible extend of admission with a maximum of three days.
- A follow up of 6 months with 4 visits of approximately 30 minutes with a standard physical examination.

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. Hospital admission because of clinically validated acutely decompensated heart failure.
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. Patients in cardiogenic shock at admission requiring invasive treatment.
8. Signed informed consent for any current interventional study.
9. Presence of severe non-cardiac related life-threatening disease before inclusion with an expected survival of less than 6 months after inclusion.
10. Mental of physical status not allowing written informed consent.
11. Unwillingness to give informed consent.
12. 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2011
Enrollment:	362
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	15-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 21346
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	3279
CCMO	NL36873.018.11
OMON	NL-OMON21346