Feasibility Of continuous non-invasive blood pressure measurement in cardiac Resynchronization ThErapy

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To demonstrate that CNBP can be used for CRT device settings adjustment aimed atoptimization of clinical status of chronic HF patients

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

Summary

ID

NL-OMON36535

Source
ToetsingOnline

Brief title
FORTE-study

Condition

- Heart failures

Synonym
failure of pumpfunction of the heart, Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: electrophysiology, heart failure, hemodynamics

Outcome measures

Primary outcome

Difference of 3.5% in left ventricular ejection fraction between both

strategies measured by 3-D echocardiography.

Secondary outcome

Changes in NYHA classification, NT-pro-BNP, 6-MWT, and QOL score assessed by the

Minnesota Living with Heart Failure questionnaire, LVEDD, LVESD, LVEDV and

LVESV, MR, incidence of ventriculartachycardia

or fibrillation (VT, VF), ICD delivered antitachycardia pacing (ATP) and

shocks, days of hospitalization

for or associated with worsening HF and mortality of any cause.

Study description

Background summary

In selected heart failure (HF) patients cardiac resynchronization therapy (CRT) is an accepted treatment. However, a consistent percentage of patients show no benefit after CRT. Improvement of hemodynamic and clinical status after changing the initial settings of a CRT device after implantation has been suggested.
Currently, there is no general consensus on the best tool to evaluate the effectiveness of changes of device setting. Although being time consuming and operator dependent, at present echocardiography (TTE) is the most widely used tool. An alternative, easy and accurate method for the identification of hemodynamic changes is continuous non-invasive blood pressure measurement (CNBP). Three studies have demonstrated acute hemodynamic improvement in patients following CRT device settings adjustments using CNBP. However, in none

of these studies follow-up assessment of clinical outcome was performed.

Study objective

To demonstrate that CNBP can be used for CRT device settings adjustment aimed at optimization of clinical status of chronic HF patients

Study design

This is a randomized, single-blinded, treatment crossover, prospective study. Patients will be randomized (1:1) to 1) CNBP-guided device settings adjustments of atrioventricular (AV-) and interventricular (VV) delay 1-2 weeks after device implantation aimed at improvement of cardiac output and dP/dt, or 2) *No adjustments* using a standard AV- and VV delay. Different HF endpoints will be assessed at 3 months follow-up and crossover to the other strategy will take place. After another 3 months follow-up (6 month after device settings adjustments) the same HF endpoints will be assessed. Differences between both strategies will be evaluated by comparing the measured endpoints.

Study burden and risks

CNBP may be useful for device adaptations aimed at optimization of the clinical status of chronic HF patients. Being noninvasive, all risks can be considered negligible.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) End stage heart failure with NYHA class II, III or IV despite optimal medical treatment 2) QRS duration > 120msec for patients in NYHA class III or IV, QRS duration > 150msec for patients in NYHA class II
3) Left ventricular ejection fraction < 35%

Exclusion criteria

1) Age < 18 years
2) Planned revascularization therapy or reparative cardiac surgery <6 months
3) Expected heart transplantation <1 year
4) Severe heart failure with short (<6 months) life expectancy
5) Chronic atrial fibrillation

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	30-11-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2012
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
Other	In behandeling
CCMO	NL27701.100.09