MUSCULAR COUNTER PULSATION IN ACUTELY DECOMPENSATED HEART FAILURE

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26361

Source
Nationaal Trial Register

Health condition

heartfailure, muscle counter pulsation, hartfalen,

Sponsors and support

Primary sponsor: Maastricht Univarstiait Medisch Centrum, dept of Cardiology
Source(s) of monetary or material Support: Maastricht Univarstiait Medisch Centrum, dept of Cardiology

Intervention

Outcome measures

Primary outcome

The primary endpoint is the effect of MCP on the combination of the cumulative diuretic dosage and length of hospital stay.

Secondary outcome

a. To evaluate the effect of MCP on muscular function / strength
b. To evaluate the effect of MCP on renal function
c. To evaluate the effect of MCP on biomarkers known to be important in heart failure
d. To evaluate the effect of MCP on the use of positive inotropic substances/ mechanical devices such as e.g. IABP
e. To evaluate the effect of MCP on quality of life (36-item Short Form (SF-36)), impact of heart failure on daily living (Kansas City Cardiomyopathy Questionnaire (KCCQ))
f. To evaluate the effect of MCP on length of hospital stay
g. To evaluate the feasibility of usage of MCP in everyday acute cardiac care on ICU and peripheral ward
h. To evaluate the effect on mortality and re-hospitalisation assessed at 30 days after discharge

Study description

Study objective

Muscular counterpulsation (MCP) is a new treatment option which seems to improve hemodynamics but might also have positive effects on muscular and vascular function. Additionally, it is non-invasive and does not seem to have relevant side effects. So far, it has been tested in different setting including stable, chronic HF or coronary artery disease. Objective: The aim of the study is to evaluate the effect of MCP in acutely decompensated HF with the primary objective being its effect on the cumulative amount of diuretics needed and the length of the hospital stay.

Study design

hospital stay, 30 days form discharge

Intervention

All patients will receive standard HF therapy as applied in all our patients being hospitalized with ADHF. Additionally, patients in the treatment group will be provided with an MCP device (m.pulse, Cardiola AG, Winterthur, Switzerland) which consists of a pulse generator with electrocardiogram (ECG) sensors, stimulation pads, and a patient-operated control unit. Via external electrodes, peripheral muscles are stimulated at early diastole using an ECG-triggered control unit and pulse generator. The electric stimuli consist of biphasic square wave pulses with a duration of 1 ms. The product of stimulation frequency (default about 200 Hz) and the voltage amplitude (max. 45 V) determines the intensity of skeletal muscle activation. It is aimed at generating a visible muscle contraction without causing discomfort to the patients. Thus, patients may adjust the applied intensity for each stimulation site separately. The electric stimuli will be given during 3 sessions per day. Each session has a duration of minimal 1 hour and maximal 2 hours.

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Eligibility criteria

Inclusion criteria

a. NYHA class III+ or IV on admission
b. Clinical signs of cardiac decompensation are clearly present at inclusion into the study
c. NT-pro BNP >800 pg/ml
d. Need for intravenous therapy with loop diuretics (e.g. bumetanide) and/or nitro-glycerine

Exclusion criteria

a. Systolic BP >180mmHg (despite treatment) or < 80mmHg
b. Cardiogenic shock
c. Clinical need for intravenous inotropic medication (excluding digoxin)
d. Need for mechanical therapy (e.g. IABP or invasive ventilation)
e. Prior cardiac transplantation or need for urgent transplantation
f. Acute coronary syndrome within 7 days prior to inclusion
g. Hypertrophic cardiomyopathy, restrictive cardiomyopathy and (sub-) acute myocarditis
h. Severe valvular disease, uncorrected
i. Need for cardiovascular surgical procedure within the following 6 months or within 3 months prior to inclusion
j. Ventricular arrhythmia (repeated with >20% ectopic beats)

k. Atrial fibrillation (HR>100 bmp)
l. Sinus rhythm >120 bpm
m. Bradycardia <60 bpm
n. Deep venous thrombosis
o. Pulmonary emboli
p. Significant systemic infection (e.g. pneumonia)
q. Patient life expectancy of <1 year for non-cardiac reasons
r. Known severe diabetes polyneuropathy
s. Age <18 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4839
NTR-old	NTR4963
Other	: abr 51863

Study results