MUSCULAR COUNTER PULSATION IN ACUTELY DECOMPENSATED HEART FAILURE

Gepubliceerd: 13-01-2015 Laatst bijgewerkt: 18-08-2022

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....

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26361

Bron
NTR

Aandoening

heartfailure, muscle counter pulsation, hartfalen,

Ondersteuning

Primaire sponsor: Maastricht Univarstiait Medisch Centrum, dept of Cardiology
Overige ondersteuning: Maastricht Univarstiait Medisch Centrum, dept of Cardiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

hospital stay, 30 days form discharge

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4839
NTR-old	NTR4963
Ander register	: abr 51863

Resultaten