MUSCULAR COUNTER PULSATION IN ACUTELY DECOMPENSATED HEART FAILURE

Published: 17-06-2015
Last updated: 14-04-2024

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

Summary

ID

NL-OMON45215

Source
ToetsingOnline

Brief title
MCP in HF

Condition

- Heart failures

Synonym
diminished pump function of the heart, Heartfailure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: heartfailure, mcp

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 due to decompensated heart failure

Secondary outcome

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Study description

Background summary

Heart failure (HF) is a frequent disorder with acute decompensations leading to a relevant number of hospitalisations and a worsening in prognosis. Still, there are only few therapeutic options (e.g. diuretics, nitrates or positive inotropic agents) none of which has shown to improve prognosis in acute decompensated heart failure (ADHF). Additionally, HF leads to muscle wasting which is accentuated in phases of immobilisation as during hospitalisation. Besides medication, other support systems such e.g. intra-aortic balloon pumps have been used with the disadvantage of being invasive. 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.

Study 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 due to decompenstaed heart failure . Secondary objectives are changes in renal function, quality of life, use of positive inotropic agents or support systems, mortality and muscular function.

Study design

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. Each application will be three times 120 minutes per day.

Intervention

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Study burden and risks

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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

NYHA class III+ or IV on admission
Clinical signs of cardiac decompensation are clearly present at inclusion into the study
NT-pro BNP >800 pg/ml

Exclusion criteria

Systolic BP >180mmHg (despite treatment) or < 80mmHg
Cardiogenic shock
Clinical need for intravenous inotropic medication (excluding digoxin)

Study design

Design

Study phase:	2
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):	15-08-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Muscular counter pulsation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-10-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL51863.068.15
Other	NTR nummer nog niet ontvangen