Dopamine on top of standard treatment for patients with exacerbation of Heart Failure, at home situation

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The primary objective of this randomized, open label single centre trial is to compare dopamine versus no dopamine on top of standard treatment in patients with exacerbation of severe heart failure (NYHA class III-IV) in home situation. This study…

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

Summary

ID

NL-OMON35847

Source
ToetsingOnline

Brief title
Do-HF

Condition

- Heart failures

Synonym
Congestive Heart Failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala klinieken (zorgvernieuwing)

Intervention

Keyword: CHF, Heart Failure, Home treatment

Outcome measures

Primary outcome

• Unplanned hospital admission for Heart Failure

Secondary outcome

• Weight reduction

• Renal impairment (elevation in serum creatinine by more than 40 micromoles/L)

• Pro-BNP level

• Absolute need of inotropicum

• Occurrence of arrhythmia, hypertension, anginal pain, nausea, vomiting, and

headache

• Pharmacy-economical efficiency of the treatment

Galectin-3 value

Study description

Background summary

Acute HF is defined as gradual or rapid changes in signs and symptoms of HF that require urgent therapy. 3 In acute decompensated heart failure, the immediate goal is to re-establish adequate perfusion and oxygen delivery to end organs. 4 Initial therapy of acute decomposated HF usually includes combination of an vasodilator such as nitroglycerine, diuretics, oxygeen supply and morfine. Inotropics, like dobutamine en dopamine, milrinone are usually used when the asbove mentiond treatment is not sufficient. 2

The current study is a prospective, randomized single centre, open label trial. In this trial patients will be included that not need to be hospitalized for the decompensated heart failure but can be recompensted with additional diuretics intra venous at home setting. The home treatent will be accompanied

by the specialized nurses of the Chance@home team of the Isala klinieken. The patients that are randomized to Dopamine will receive 24 hours Dopamine on top of the standard treatement.

Study objective

The primary objective of this randomized, open label single centre trial is to compare dopamine versus no dopamine on top of standard treatment in patients with exacerbation of severe heart failure (NYHA class III-IV) in home situation. This study will investigate whether 24 hour dopamine infusion reduces the need of hospital admission for patients with exacerbation heart failure.

Study design

Single centre, randomized, open study

Intervention

Patients who are randomized to Dopamine will get a Dopamine infusion during 24 hours +- 6 hr.

Study burden and risks

Minimal burden due to the 24 hours Dopamine infusion and blood draw of 2 extra blood tubes (during regular blood taking)

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

Exacerbation heart failure with NYHA class III-IV

Exclusion criteria

Cardiogenic shock
Tachycardia, heart rate > 100 bpm
Indication for hospitalization
Severe aortic valve stenosis
Severe hepatic or renal disease
Patients with acute coronary syndromes
Previous participation in the study
Life expectancy of < 1 year
Absolute contra indication for the use of Dopamine
Women of child-bearing potential
Unable to provide informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2011
Enrollment:	110
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dopamine HCl
Generic name:	Dynatra Dopamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-06-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	11-08-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
EudraCT	EUCTR2011-002236-92-NL
CCMO	NL36932.075.11