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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23078

Source
NTR

Brief title
Do-HF

Health condition

Heart failure, home treatment, NYHA 3-4

Hartfalen, thuisbehandeling, NYHA 3-4

Sponsors and support

Primary sponsor: Isala klinieken
Groot wezenland 20
8011 JW Zwolle
The Netherlands
Source(s) of monetary or material Support: Isala klinieken
Groot wezenland 20
8011 JW Zwolle
The Netherlands

Intervention

Outcome measures

Primary outcome

Unplanned hospital admission for Heart Failure.

Secondary outcome

1. Weight reduction;

2. Renal impairment (elevation in serum creatinine by more than 40 micromoles/L);

3. Pro-BNP level;

4. Absolute need of inotropicum;

5. Occurrence of arrhythmia, hypertension, anginal pain, nausea, vomiting, and headache;

6. Pharmacy-economical efficiency of the treatment.

Study description

Background summary

This study will investigate if 24 hours of Dopamine infusion 2 µg/kg/min at home situation, on top of standard treatment, can increase successful home treatments.

In patients presenting in hospital with exacerbation of heart failure (NYHA III-IV) that are candidate for home treatment.

Study objective

This study will investigate whether 24 hour dopamine infusion reduces the need of hospital admission for patients with exacerbation heart failure.

Study design

1. Baseline;

2. Start treatment;

3. 24 hr after start treatment;

4. End home treatment;

5. 30 days follow-up.

Intervention

In this trial patients will be included that don't need to be hospitalized for the decompensated heart failure but can be recompensated with additional diuretics intra venous at home setting. The home treatment 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 treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Males or females ≥ 18 years of age;

2. Heart failure with NYHA class III-IV.

Exclusion criteria

1. Cardiogenic shock;

2. Tachycardia, heart rate > 100 bpm;

3. Indication for hospitalization;

4. Severe aortic valve stenosis;

5. Severe hepatic or renal disease;

6. Patients with acute coronary syndromes;

7. Previous participation in the study;

8. Life expectancy of < 1 year;

9. Absolute contra indication for the use of Dopamine;

10. Women of child-bearing potential;

11. Unable to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	110
Type:	Actual

Ethics review

Positive opinion

Date:	28-07-2011
Application type:	First submission

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	NL2863
NTR-old	NTR3006
Other	METC / CCMO : 2011-002236-92 / NL36932.075.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A