Evaluation of a temporary pump in patients with decompensated heart failure

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26259

Source
NTR

Brief title
IABP-HF

Health condition

Cardiogenic shock, heart failure

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

Delta SvO2 (T3h minus baseline T0h (=mean of two baseline measurements with interval 15 minutes)).

Secondary outcome

- Cardiac power output at T=24h (absolute and change vs baseline).

- NT-proBNP levels at T=48h (absolute and change vs baseline).

- Negative fluid balance of at least 1L at T48h.

- Patient Global Assessment: Dyspnea Severity Score or Visual Analogue Scale at T=48h (absolute and change vs baseline).

- Escalation of therapy.

- Duration of hospital stay.

- Major adverse cardiac events (MACE, = combined endpoint of escalation of therapy, death, heart failure rehospitalization, TIA/stroke). To assess at 30 days and 3 months.

Study description

Background summary

Rationale: In severe heart failure, the heart¡¯s pumping power is weak, leading to fluid retention and hospital admission of the affected patient. This project will investigate if a temporary pump (intra-aortic balloon pump, IABP) in the aorta will treat fluid overload so that patients are bridged faster towards recovery or to surgical assist device implantation.

Objective: Evaluation of the benefit of IABP counterpulsation in patients with diuretic-resistant congestive heart failure.
Secondary objectives:

• To lower the burden of disease/improve symptoms, to shorten duration of stay in the hospital, to improve the function of other organs than the heart, and to bridge patients faster to final treatment (medical vs. LVAD vs. transplantation vs. palliative care).

• To create evidence based knowledge and gain better understanding of the disease, resulting in tailor-made treatment.
Study design: Open-label randomized controlled parallel, partial cross-over, study in patients with diuretic-resistant congestive heart failure.

Study population: Patients with congestive heart failure, refractory to treatment with high dosages of intravenous diuretics.

Intervention (if applicable): Patients will be randomized to IABP (without inotrope, group I) or

inotrope (without IABP, group II).
Main study parameters/endpoints: Delta SvO2 at T=3h.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients in evident heart failure refractory to high-dose diuretic therapy have a poor prognosis. Escalation therapy will be given by either inotropic therapy (carrying the risks of arrhythmias) or an IABP (carrying the risks of access site and remote complications, <1%). Both treatment options have been successfully applied to save patients.

Study objective

In severe heart failure, the heart¡¯s pumping power is weak, leading to fluid retention and hospital admission of the affected patient. This project will investigate if a temporary pump (intra-aortic balloon pump, IABP) in the aorta will treat fluid overload so that patients are bridged faster towards recovery or to surgical assist device implantation.

Study design

T=0h, T=3h, T=12h, T=24h, T=48h, T=72h.
At T=48h, a crossover will be performed in clinical non-responders as defined by protocol.

Intervention

Intra-aortic balloon pump vs inotropic therapy

Contacts

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Eligibility criteria

Inclusion criteria

CONGESTIVE HEART FAILURE (FIRST EPISODE (¡°DE NOVO¡±) OR WORSENING OF CHRONIC HEART FAILURE) WITH THE FOLLOWING CHARACTERISTICS:

BLOOD PRESSURE Systolic <100 mm Hg

PHYSICAL EXAMINATION Fluid retention (elevated central venous pressure, palpable liver, edema)

ECHO At least moderate tricuspid regurgitation and/or mitral valve regurgitation. Dilated inferior caval vein.

INVASIVE MEASUREMENTS PCWP >15 mmHg; CVP >12 mmHg; SvO2 <55%

NT-PROBNP >200 pg/mL

FLUID BALANCE Neutral or positive despite fluid restriction (1.5L/24h) and administration of high dosages of intravenous diuretics*

TOGETHER WITH: Dysfunction of at least 1 other organ#
PCWP, pulmonary capillary wedge pressure; CVP, central venous pressure.

* Bolus dosage (equal to) 80 mg intravenous furosemide followed by total intravenous dosage equal to total daily loop diuretic dose in furosemide equivalents and (if necessary) doubled, for at least 12h.

Lung: extra oxygen supplementation, kidney: creatinine clearance <50 mL/min, liver enzymes ¡Ý2x upper limit of normal, or lactate levels ¡Ý2.0 mmol/L.

Exclusion criteria

- Significant aortic valve regurgitation.

- Absent common femoral artery pulsation.

- Acute myocardial infarction <7 days before inclusion.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-10-2016
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	NL5979

Register	ID
NTR-old	NTR6143
Other	: MEC-2016-475

Study results