Evaluation of a temporary pump in patients with decompensated heart failure.

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Primary Objective: Evaluation of the benefit of IABP counterpulsation in patients with diuretic-resistant congestive heart failure. Secondary Objective(s): - To lower the burden of disease/improve symptoms, to shorten duration of stay in the...

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

Summary

ID

NL-OMON43519

Source
ToetsingOnline

Brief title
A temporary pump in heart failure (IABP-HF).

Condition

- Heart failures

Synonym
a failing heart, Decompensated heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Decompensated heart failure., Inotropes., Intra-aortic balloon pump., Mechanical circulatory support device.

Outcome measures

Primary outcome

Delta SvO2 (T3h minus baseline T0h (=mean of two baseline measurements with

interval 15 minutes)).

Secondary outcome

Secondary endpoints:

- 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.

- Sublingual perfused capillary density (=microcirculation) at T=24h.

- Contrast-enhanced ultrasound of renal perfusion at T=24h.

- Patient Global Assessment: Dyspnea Severity Score or Visual Analogue Scale at

T=48h (absolute and change vs baseline).

- Escalation of therapy (Table 3).

- 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.

Other study parameters

- Initiation of renal replacement therapy.

- IABP-related complications (bleeding according to BARC criteria, infection,

access site complications according to VARC-2 criteria).

- Final result of treatment to be recorded at hospital discharge: Bridge to

chronic heart failure with good quality of life, LVAD, heart transplantation,

palliative care.

Study description

Background summary

Introduction:
Patients with heart failure have a diminished cardiac pump function. Severe congestive heart failure is characterized by signs and symptoms of severe left ventricular failure. Patients have fluid retention and other signs such as right ventricular dysfunction, renal dysfunction or pulmonary congestion. These patients are admitted to a heart failure clinic for weeks, and often longer than one month. They are treated with (high dosages of) intravenous diuretics. When basic treatment fails, mortality rates are high. Escalation therapy includes administration of inotropic drugs (-> these enhance cardiac contractility) such as enoximone or dobutamine. Guidelines note that initiation of inotropic therapy *may be reasonable* in diuretic-resistant patients. However, there are no data demonstrating an outcome benefit of inotropes in this population, and some reports warn for the potential adverse events including increased mortality. Moreover, inotropes also often fail to rapidly improve the patient. In these patients, escalation towards mechanical circulatory support such as an intra-aortic balloon pump, is necessary. When right heart and kidney function deteriorate in case of failing therapy, patients have contra-indications for implantation of a (permanent) left ventricular assist device (LVAD) and/or heart transplantation.
Shortcomings of the current approach therefore include:
-> current treatment often fails;
-> it consumes at least weeks to learn if right ventricular and renal function recover sufficiently in order to qualify for LVAD implantation, and
-> patients are thus admitted in the hospital for a long period of time.

Rationale:
In Erasmus MC, we treated several advanced heart failure patients with an intra-aortic balloon pump (IABP). This IABP was used as a bridge to recovery (ie, towards ambulant heart failure in good global condition), as a bridge to implantation of LVAD or heart transplantation, or to palliative care. An IABP

is a pneumatic, helium gas driven balloon catheter, positioned in the descending aorta to improve heart function.
Complication rates of this pump are low (<1%). In heart failure patients, I observed a decrease in dyspnea and fluid retention after implantation of the pump (Figure 2), which was also described in observational studies of other investigators. The use of the IABP for diuretic-resistant heart failure however remains controversial, mainly due to the lack of strong data. I would very much like to investigate these observations more comprehensively and we urgently need controlled trials in order to develop an evidence-based treatment algorithm for tailored patient treatment.

Study objective

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

Secondary Objective(s):
- 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

Study design: Open-label randomized controlled parallel, partly cross-over, study in patients with diuretic-resistant congestive heart failure (Figure 3).

Duration: Three years.

Setting: 12-bed Intensive Cardiac Care Unit at Erasmus MC.

Intervention

Methods: Each patient will receive a pulmonary artery catheter to measure intracardiac pressures. After informed consent, patients will be randomized (Figure 3) to IABP (without inotrope, group I) or inotrope (without IABP, group II).
After 48 hours, we aim at a negative fluid balance of at least 1 liter. If this target (+ 1 other criterium; Table 2) is not reached, a patient is classified as clinical *non-responder*by protocol. In these non-responders, a crossover of the protocol will be performed using the same endpoints. After 48h (or 96h in case of a non-responder), patients will receive routine treatment: in general the pump or inotropes will bridge the patient towards recovery or LVAD implantation.

TABLE 2. DEFINITION OF NON-RESPONDER, ASSESSED AT T=48H
FLUID BALANCE AT T=48H Less than 1 liter negative
AND 1 OTHER CRITERIUM:
- SVO2 (T=48H) <55%
- LACTATE (T=48H) >2.0 mmol/L.

Group 1 (IABP): An experienced interventional cardiologist will implant the IABP in the catheterization laboratory. The IABP catheter will remain in situ for at least 48h, unless complications occur or escalation of therapy is necessary.

Group II (Inotrope): Enoximone will be started in a dose of 1 µg/kg/min. Before starting the infusion, a bolus injection will be given equal to the volume of the (central) venous line used. Target dose will be 0.5-2 µg/kg/min, based on the following parameters:
- Cardiac index (if measured reliably; target >2.5 L/min/m2).
- SvO2 (target >55%)
- Lactate (target <2.0 mmol/L).
- Mean arterial pressure (MAP, target *60 mm Hg).
- Urine output (target >0.5 mL/kg/uur).
If necessary, dobutamine can be added in a dose of 1-10 µg/kg/min, dependent of the parameters listed above, heart rate (target 60-120 bpm) and the occurrence of arrhythmias.

Escalation of therapy (Table 3; Word file):
Escalation therapy is defined as (unintended) extension of therapy based on clinical assessment of the patient after T=3h, but within T=48h.
In the IABP group (group I), escalation of therapy could be performed by starting an inotropic agent (=enoximone or dobutamine), or norepinephrine.
Indication for starting inotropic therapy is failure of therapy, defined as SvO2 <55% AND lactate *2.0 mmol/L AND low urine output (<0.5 mL/kg/h).
Indication for starting norepinephrine is prolonged hypotension (MAP <60 mm Hg for at least 30 minutes) AND low urine production (<0.5 ml/kg/uur).
In the inotrope group (group II), escalation of therapy could be performed by (a) starting norepinephrine and (b) implantation of an IABP.
Indication is failure of therapy, defined as SvO2 <55%, lactate *2.0 mmol/L, prolonged hypotension (MAP <60 mm Hg for at least 30 minutes) AND low urine production (<0.5 mL/kg/uur).
In both groups, escalation towards more potent circulatory support devices or extracorporeal membrane oxygenation is always indicated in cases of evident treatment failure, defined as progressively worsening SvO2 and lactate measures despite high dosages of inotropic and vasopressor support, and IABP.

Study burden and risks

Therapy with inotropes as well as intra-aortic balloon pump support are frequently used in patients with heart failure. Complication rates are low

(<1%). Decompensated heart failure is a CE-certified indication for an intra-aortic balloon pump.

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

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 PCWP >15 mm Hg; CVP >12 mm Hg; 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 (kidney, liver, lactate)

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Intra-aortic balloon pump (IABP)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL56452.078.16