RV Impella support as a bridge-to-recovery in right ventricular failure

Gepubliceerd: 27-07-2017 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22623

Bron
NTR

Aandoening

right ventricular failure

mechanical circulatory support

LVAD

Dutch: rechterkamerfalen, mechanische hartondersteuning, LVAD

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The occurrence of major bleeding, hemolysis, thrombus formation in RA/RV/PA, right heart valve dysfunction and tamponade from device implantation up to 30 days or hospital discharge after device removal and the occurrence of arrhythmias during device implantation

Toelichting onderzoek

Achtergrond van het onderzoek

Right ventricular failure refractory to medical therapy is a complication that can arise post-LVAD implantation, after a conventional cardiac surgical procedure or as a consequence of an acute myocardial infarction (MI). It is associated with significant morbidity and mortality. Short-term mechanical support of the RV may be beneficial for these patients as a bridge to recovery, as has been demonstrated in several previous studies involving invasive devices such as TandemHeart or surgically implantable RVADs. Recently, however, a more readily available and minimally invasive percutaneous support device for the RV has been developed for this purpose. The primary objective of the study is to evaluate local implementation, safety, feasibility and efficacy of temporary RV support with the Impella RP circulatory support device. The secondary objective is to evaluate the effect of temporary RV support on several clinical and hemodynamic parameters, to develop a ‘safety-net’ for potential LVAD-candidates at risk for transient postoperative RV dysfunction, to further expand and develop expertise in the field of short-term mechanical circulatory support also with regard to right heart failure. After evaluation of in-and exclusion criteria and after obtaining informed consent, the Impella RP percutaneous right ventricular assist device is implanted in patients with RV failure refractory to medical treatment, who are being monitored in the intensive cardiac care unit (ICCU) or intensive care unit 1 (ICV1). The primary safety endpoint is the occurrence of bleeding (BARC type 2 and above) including tamponade & access site, hemolysis, thrombus formation in RA/RV/PA, right heart valve dysfunction, and arrhythmias up to 30 days after implantation. The primary efficacy endpoints are improvements in cardiac index, inotrope dosage, LVAD flow, pump parameters, urine production, lactate and SvO2 compared to baseline and 4 and 24 hours after implantation.

Doel van het onderzoek

the prognosis of patients with severe RV failure after LVAD-implantation, post-cardiotomy or post-MI is grim, as medical treatment options are scarce. In a previous study, treatment with the Impella RP has been proven to be safe, feasible and potentially efficacious. Nevertheless, it may be associated with potential complications such as major bleeding, thrombus formation and damage to the right-sided heart valves. Within the current study, we aim to evaluate local implementation of the device into clinical practice.

Onderzoeksopzet

Baseline, T=4 h, T=24 h, T=48 h, 30 days, 6 months

Onderzoeksproduct en/of interventie

Implantation of RV Impella

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age >18 years of age

- Setting: post-LVAD, post-cardiotomy, post-myocardial infarction

- Refractory RV failure, defined as a cardiac index of <2.2 l/min/m2 despite inhaled nitric

oxide, continuous infusion of high-dose inotropes (dobutamine >10ug/kg/min or equivalent for >120 minutes) or the administration of >1 vasopressor/inotrope AND at least 1 of the following:

-central venous pressure (CVP) >18 mmHg

-CVP/pulmonary capillary wedge pressure or left atrial pressure ration of >0.63

-global echocardiographic RV dysfunction, defined as a tricuspid annular systolic excursion (TAPSE) of <16mm, RV base diameter of >42 mm or RV short-axis/midcavity diameter of >35 mm

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Definite exclusion criteria

-profound cardiogenic shock, defined as a cardiac index of <1.3 and signs of irreversible multi-organ failure despite infusion of inotropes and/or vasopressors and LVAD therapy

-SOFA score >10

-the presence of a thrombus in the right atrium, right ventricle or pulmonary artery

-mechanical prosthetic tricuspid or pulmonary valve

-severe tricuspid or pulmonary valve stenosis

-pulmonary embolism

-anatomic conditions precluding pump insertion

-documented deep venous thrombosis or presence of an inferior vena cava filter

Relative exclusion criteria

-severe pulmonary hypertension, defined as a systolic pulmonary artery pressure of >60mmHg

-RV failure post-cardiac transplant

-severe tricuspid or pulmonary valve regurgitation

-severe active infection, defined as 2 or more of the following: a temperature of >38.5 C or <35.5 C, WBC of >12 000 or <4 000, heart rate of >90 bpm and respiratory rate of >22/min

-known coagulopathy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6562
NTR-old	NTR6743
Ander register	: Informatie niet aangeleverd door onderzoeker

Resultaten