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

Published: 08-06-2018
Last updated: 12-04-2024

Primary objective: To evaluate local implementation, safety, feasibility and efficacy of temporary RV support with the Impella RP circulatory support deviceSecondary objective: -To evaluate the effect of temporary RV support on several clinical and...

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

Summary

ID

NL-OMON46615

Source
ToetsingOnline

Brief title
RV Impella as bridge to recovery

Condition

- Heart failures

Synonym
heart failure, right ventricular 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: LVAD, Mechanical circulatory support, RV failure

Outcome measures

Primary outcome

Primary safety endpoint: 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

Primary efficacy endpoint: 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

Secondary outcome

Secondary safety endpoint: MACE @ 30 days

Secondary efficacy endpoints:

• Successful weaning

• Duration of implantation procedure

• TAPSE, S RV and RV diameters compared to baseline at 24 and 48 hours after implantation, after device removal and at 30 days/before hospital discharge

• ICU and hospital length of stay

• Survival at 30 days and 6 months

Study description

Background summary

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.

Study objective

Primary objective:
To evaluate local implementation, safety, feasibility and efficacy of temporary RV support with the Impella RP circulatory support device

Secondary objective:
-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

Study design

a prospective, non-randomized, non-blinded safety-and-feasibility study

Intervention

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).

Study burden and risks

Implantation of and treatment with the Impella RP4.0 percutaneous right ventricular assist device is associated with certain risks. However, patients included in this study, suffering of medical treatment-refractory RV failure, have a dismal prognosis. As these patients could benefit from support with the Impella RP4.0 device, the risk-benefit ratio is acceptable.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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 ratio 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

Exclusion criteria

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
-implantation of permanent pacemaker within three months before study inclusion

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-01-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Impella RP4.0
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-06-2018
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
Other	27592
CCMO	NL62837.078.17