CIP Pulsecath iVAC2L in High-Risk PCI patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON39763

Source
ToetsingOnline

Brief title
Pulsecath iVAC2L

Condition

- Coronary artery disorders
- Vascular therapeutic procedures
- Vascular hypertensive disorders

Synonym
coronair sclerose

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Leverancier van Pulsecath cath stelt deze cath gratis ter beschikking

Intervention

Keyword: Cardiac assist Device, high risk PCI patient

Outcome measures

Primary outcome

The application of the device is considered safe when:

1) MACE < 20%

2) the degree of hemolysis was manageable

The efficacy of the device is considered established when:

1) the surgical introduction, positioning, fixation and removal of the iVAC2L

has been

performed without any injury of valvular or vascular structures, and the device

has not

caused perfusion disorders of the peripheral arteries

2) the hemodynamic parameters could be maintained according to the following

limits:

Cardiac Index > 2.5 L/min/m2; Mean Arterial Pressure > 60 mmHg, during the whole

duration of support by the iVAC2L

Clinical success is achieved when the patient has successfully been weaned from

the

device.

Secondary outcome

N.A.

Study description

Background summary

The PulsCath iVAC2L-heart pump is a newer version of an existing heart pump, which is already on the market. Before the newer version can be registered, investigation with patients should be done. This study is designed to demonstrate that the pump is safe in use, and can assist to maintain sufficient circulation.

Study objective

The primary objective is to evaluate the safety and efficacy of the PulseCath iVAC2L in highrisk
PCI patients who require left ventricular assistance. Safety will be assessed by the
incidence of Cerebrovascular Accidents (CVA*s), thrombo-embolic events and the amount of
blood cell damage (hemolysis). Efficacy will be assessed in terms of technical success and
hemodynamic performance of the device.

Study design

The study is a prospective single-centre, single-arm feasibility study.
The study will be performed in the hospital of the principal investigator.
Twent (20) patients will be included in the study and followed up to 1 day after weaning of the iVAC2L, or, when earlier, to discharge.
The study will run for a period of maximal 12 months.

Intervention

prior to or during the treatment, the pulscath iVAC2L heart pump will be inserted according to standard hospital prescription

Study burden and risks

Risks are valued as "high"
During use of the iVAC2L pump, the following measurements will be done:
invasive hemodynamics
blood tests to monitor anticoagulant, liver and kidney functions.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Indicated for High-Risk PCI, according to hospital standard procedure
* Indicated to have an IABP during the PCI, according to hospital standard procedure
* Expected duration of iVAC2L support: maximum 24 hours
* Patient older than 18 years
* Patient has signed the Informed Consent

Exclusion criteria

* Aortic disease: ascending aortic aneurism, severe calcified aorta
* Aortic valvular disease: severe aortic valve stenosis, severe aortic valve insufficiency
* Aortic mechanical valve prosthesis

* Thrombus in left ventricle
* Intra ventricular septum defect
* Severe peripheral vascular disease
* No functioning right ventricle
* History of coagulation disorders
* Participation in another clinical study that may interfere with this study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2013
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Catheterpump
Registration:	No

Ethics review

Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-01-2015

Application type:	Amendment
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	NL41304.078.13