effect of a higher bloodpressure on Right Ventricular Function

Published: 17-01-2019
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To demonstrate differences in RV function by raising the systemic blood pressure with norepinephrine.

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

Summary

ID

NL-OMON48144

Source
ToetsingOnline

Brief title
Effect of a higher bloodpressure on the RV function

Condition

- Heart failures

Synonym
bloodpressure, right ventricular function

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Intensive Care Onderzoek Leeuwarden

Intervention

Keyword: blood pressure, cardiac surgery, right ventricular function

Outcome measures

Primary outcome

Primary endpoint is a difference in RV ejection fraction

Secondary outcome

Secondary endpoints are the echocardiographic parameters of RV and LV

contractility, RV end-diastolic pressure, cardiac index, and fluid balance.

Study description

Background summary

Right ventricular (RV) dysfunction in cardiac surgery is an independent risk factor for morbidity and mortality. Raising the systemic blood pressure with norepinephrine seems to have a positive influence on the function of the right ventricle in several animal studies. The current study is designed to evaluate the effect of a higher blood pressure on the RV function in post cardiac surgery patients.

Study objective

To demonstrate differences in RV function by raising the systemic blood pressure with norepinephrine.

Study design

randomized controlled trial

Intervention

Intervention:
* Group 1: (N=22): RVEF<20% and MAP<70mmHg. Intervention with norepinephrine to reach a MAP of 85mmHg for a maximum duration of four hours.
* Group 2: (N=22): RVEF <20% and MAP<70mmHg. Control group: treatment according to current standards. Hypotensive patients are treated with fluids and/or

vasopressors to gain a mean arterial pressure (MAP) of 65mmHg.
* Group 3: (N=17): RVEF between *20 and <30%. Intervention with norepinephrine to reach a MAP of 85mmHg for a maximum duration of four hours.
* Group 4: (N=17): RVEF between *20 and <30%. Control group: treatment according to current standards. Hypotensive patients are treated with fluids and/or vasopressors to gain a mean arterial pressure (MAP) of 65mmHg.

Study burden and risks

Norepinephrine will be used to raise the systemic blood pressure to asses our end-points. Since the use of Norepinephrine falls within therapeutic routine, the potential risks are low. Furthermore, all patients will undergo transoesophageal echocardiography in the postoperative setting. The expected risk and disadvantages are small. Only minor discomfort is expected because all patients are sedated during the investigation.

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

- age > 18
- sedated patients
- after cardiac surgery
- informed consent

Exclusion criteria

- acute surgery

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2019
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2019
Application type:	First submission

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	clinical trial nr volgt
CCMO	NL67901.099.18

Study results

Date completed:	25-05-2020
Actual enrolment:	78