Continuous Postoperative Pericardial Flush (CPPF); to evaluate the effects of pericardial flush with a crystalloid on blood loss after valvular surgery and correction for congenital heart disease (CHD).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27629

Source
Nationaal Trial Register

Brief title
CPPF

Health condition

Postoperative blood loss, Cardiac tamponade, Transfusion requirements, Surgical reexploration

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam, The Netherlands
Source(s) of monetary or material Support: Academic Medical Center (AMC), Amsterdam, The Netherlands

Intervention

Outcome measures

Primary outcome

1: Mediastinal chest tube drainage (MCTD) 12 hours postoperatively.

2: The difference in hemoglobin levels between the start of CPPF and 12 hours postoperative (ΔHb).

Secondary outcome

Cardiac tamponade, Transfusion requirements, Surgical reexploration, Postoperative atrial fibrillation, sternal wound infection, mediastinitis, Length of ICU stay and hospitalization, Pericardial and/or pleural effusion at discharge, In-hospital mortality, Mortality, Right ventricular function at six months postoperatively

Study description

Study objective

Continuous postoperative pericardial flush (CPPF) with a crystalloid is likely to enhance the evacuation of activated and contaminated pericardial blood and cloths out of the pericardial cavity and may contribute to a reduction of (excessive) blood loss and here related transfusion requirements and need for re-operation for bleeding after cardiac surgery. Flushing the pericardial cavity is likely to reduce the amount of cloths and old blood remains after removal of the chest tubes and consequently, the incidence of early and late cardiac effusions and tamponade may be reduced.

Study design

T-1 = Randomization, T0 = Arrival on ICU, T12 = 12 hours postoperatively, T24 = 24 hours postoperatively, TD = Discharge from hospital, T6m = Follow-up six months postoperatively.

Intervention

CPPF will be performed continuously after operation (using a flushing system with a set flow rate of 500ml/hour), starting from the moment the sternum is closed until the total flushing volume of 7000ml has been completely infused.

Contacts

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Eligibility criteria

Inclusion criteria

All adult patients undergoing surgery for CHD and all adult patients undergoing valvular surgery. Valvular surgery includes single and multiple-valve procedures that involve replacement and/or repair of the aortic-, pulmonary-, mitral- and/or tricuspid valve.

Exclusion criteria

Patients are not eligible for this study if the following criteria apply:

- Inability to understand study information and/or give informed consent;

- Emergency surgery;

- Indication for treatment with statins based on the CBO-guideline for cardiovascular risk management;

- Myopathia;

- Participation in any study involving an investigational drug or device;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2013
Enrollment:	170
Type:	Actual

Ethics review

Positive opinion

Date:	14-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39811
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5070
NTR-old	NTR5201
CCMO	NL42595.018.12
OMON	NL-OMON39811

Study results