The pericardial perfusie study, to evaluate the safety and feasability of postoperative pericardial perfusion with NaCl 0.9% to reduce blood loss after cardiac surgery

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The aim of this study is to evaluate the safety and feasibility of postoperative pericardial perfusion with (prewarmed NaCl 0.9%) and the effect of perfusion on blood loss after cardiac surgery. Hypothesis Pericardial perfusion with (prewarmed NaCl...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON35280

Source
ToetsingOnline

Brief title
Pericardial perfusion study

Condition

- Cardiac therapeutic procedures

Synonym
blood loss

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pericardial perfusion

Outcome measures

Primary outcome

Evaluation of the feasibility and safety of pericardial perfusion.

Secondary outcome

Peroperative:

- Duration operation

- Duration of CPB usage

- Duration of aortic clamping

Postoperative:

- Amount of blood loss within 24 hours after surgery

- Temperature

- Radiology and echography

Study description

Background summary

Excessive postoperative blood loss (>2L/24 hours or >200 mL/hour) is one of the most common complications of cardiac surgery, and a risk factor for prolonged mechanical ventilation, pneumonia, wound infection, sepsis, and mortality. A surgical cause of bleeding is only found in half of patients undergoing reoperation/re-exploration for bleeding. In the remainder of patients the cause

is multifactorial and probably an acquired/surgical related hemostatic defect is responsible for diffuse, excessive blood loss.
During and a short period after cardiac surgery with concomitant usage of the CPB primary hemostasis, coagulation, fibrinolysis, and inflammation are activated. The addition of pericardial blood to the systemic circulation strongly promote these processes, ultimately leading to a DIC process, fibrinolysis and in some cases even increased blood loss. Allogeneic transfusions of packed red cells are often required, with the risk of transmitting infectious agents, provoking adverse immunologic reactions, and increased mortality.

Postoperative pericardial perfusion with a crystalloid (NaCl 0.9%) to remove the contaminated' pericardial blood, might reduce blood loss after cardiac surgery.

Study objective

The aim of this study is to evaluate the safety and feasibility of postoperative pericardial perfusion with (prewarmed NaCl 0.9%) and the effect of perfusion on blood loss after cardiac surgery.

Hypothesis
Pericardial perfusion with (prewarmed NaCl 0.9%) is safe and feasible and might reduce blood loss after heart surgery

Study design

Pilot , intervention study to evaluate the feasibility and safety of pericardial perfusion. Single center

Intervention

Insertion of an extra (inflow) drain in the pericardium, over which NaCl 0.9% will flow with an initial rate of 500mL/hour. The inflow will be ajusted according to the outflow, with an one on one ratio. There will be continous evaluation of in- and outflow.

Study burden and risks

The risk of the study is minor. Infection might be a possible adverse event, due to an extra inserted drain, although the chance is limited by using one incision for two drains (of which one is inserted regularly). To monitor this possible adverse event, temperature and several laboratory measurements will be determined. Fluid retention within the pleural and pericardial cavities will be monitored via a radiologic and echographic imaging, and every opened (pleural/pericardial) cavity is drained separately.

A possible benefit for a patient receiving the pericardial perfusion might be active (central) warming when a patient suffers from hypothermia. The expected decrease in blood loss and pericardial adhesions after operation, decreases the change of reoperation and its complications.

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

All adult patients undergoing cardiac surgery

Exclusion criteria

emergency surgery, history of bleeding diathesis or coagulopathy, participation in any study involving an investigational drug or device, inability to understand the study information and/or sign informed consent.

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):	01-11-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	drain
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL37960.018.11