Continuous Postoperative Pericardial Flush; to evaluate the effects of pericardial flush with a crystalloid on blood loss after CABG.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24893

Source
Nationaal Trial Register

Brief title
CPPF

Health condition

Postoperative blood loss, Cardiac tamponade, Transfusion requirements, Health-related quality of life, Cost-effectiveness.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

2: The difference in haemoglobin 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, In-hospital mortality, Hemoglobin at discharge, Pericardial and/or pleural effusion at discharge, Mortality, Right ventricular function six months postoperatively, Quality of life (EQ-5D+) six months postoperatively, Health and labour questionnaire (SF-HLQ) six months postoperatively, cost effectiveness.

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 CABG. 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 6 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 (>18y) undergoing surgery for CABG.

Exclusion criteria

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

- Previous CABG;

- Emergency surgery;

- Preoperative use of Dabigatran, Rivaroxaban, Apixaban, Clopidogrel, Brilique or Prasugrel;

- <18 years and/or inability to understand study information / give informed consent;

- 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:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	170
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44986
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5069
NTR-old	NTR5200

Register	ID
CCMO	NL43190.018.13
OMON	NL-OMON44986

Study results