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).

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27629

Bron
Nationaal Trial Register

Verkorte titel
CPPF

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam, The Netherlands
Overige ondersteuning: Academic Medical Center (AMC), Amsterdam, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	170
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39811
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten