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

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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...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24893

**Bron**
Nationaal Trial Register

**Verkorte titel**
CPPF

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC), Amsterdam, The Netherlands
**Overige ondersteuning:** ZonMw DoelmatigheidsOnderzoek Type I Program

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1: Mediastinal chest tube drainage (MCTD) at 12 hours postoperatively. <br>
2: The difference in haemoglobin 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 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.

### Onderzoeksopzet

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.

### 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

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All adult patients (>18y) undergoing surgery for CABG.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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;

## Onderzoeksopzet

## Opzet

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

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-01-2014 |
| Aantal proefpersonen: | 170 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44986
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL5069 |
| NTR-old | NTR5200 |

| Register | ID |
| --- | --- |
| CCMO | NL43190.018.13 |
| OMON | NL-OMON44986 |

# Resultaten