# Colloid Oncotic Pressure as indicator of hemodilution in cardiac surgery with cardiopulmonary bypass

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The addition of albumin or gelofusine in the predominantly crystalloid prime is beneficial for COP compared to the crystalloid only prime in cardiac surgery setting with cardiopulmonary bypass.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON22437

**Bron**
Nationaal Trial Register

**Verkorte titel**
COP trial

**Aandoening**

Coronary disease, cardiac valve disease

### Ondersteuning

**Primaire sponsor:** Amsterdam UMC, VUmc location
**Overige ondersteuning:** Amsterdam UMC, VUmc location

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

• To determine the changes in COP between different priming fluids during cardiac surgery with CPB

# Toelichting onderzoek

### Achtergrond van het onderzoek

The selection of perioperative fluids during cardiac surgery is based on physiological principles. Clinical preference largely determines clinical practice with regional variation between cardiac surgery centers in the Netherlands. The choice for the type, amount and timing of perioperative fluids during cardiac surgery, especially with the use of cardiopulmonary bypass(CPB), may affect patient-centered outcomes.

Cardiopulmonary bypass is a technique used during cardiac surgery, which reroutes blood from heart and lungs to the CPB machine, outside of the body. Normal functions, including circulation, oxygenation and ventilation, are temporarily taken over by the CPB. Priming fluid of the bypass circuit is part of a complex hemodynamic resuscitation strategy and is used to maintain an adequate circulatory volume (Doherty and Buggy 2012). Traditionally, crystalloids are used as priming volume during CPB with the advantages of reduced blood viscosity and high urine output compared to colloid fluids (Scott, Hore et al. 1995). Although, some crystalloids may cause a metabolic acid state at the onset of CPB, since unbalanced crystalloids have a low strong ion difference (SID) (Morgan, Venkatesh et al. 2004, Alston, Theodosiou et al. 2007, Liskaser 2009). Moreover, a highly positive fluid balance and weight gain could be a result of infusion of crystalloids which move into the extravascular spaces within 15-30 minutes after infusion (McIlroy and Kharasch 2003). The movement of solutes and solvents into the extravascular space during cardiopulmonary bypass may partly be explained by an increased permeability of a degraded endothelial glycocalyx layer (EGL)(Myers and Wegner 2017). Subsequently, hemodilution, tissue edema and microcirculatory dysfunction may compromise adequate oxygen delivery to the peripheral tissues and optimal end-organ perfusion (Himpe, Neels et al. 2003, Chappell, Jacob et al. 2008, Myburgh and Mythen 2013).

Fluid movement into the extravascular space was believed to be determined between two opposing forces: the hydrostatic pressure gradient (capillary pressure minus interstitial fluid (ISF) pressure) and the colloid oncotic pressure (COP) gradient (capillary COP minus ISF COP) (Starling 1896). Yet, the transcapillary fluid movement is less affected by ISF COP and fluid is not absorbed by capillary COP according to the revised Starling equation (Levick 2004). Moreover, it is the COP in the subglycocalyx that is seen as determinant of transcapillary flow instead of ISF COP (Adamson, Lenz et al. 2004, Curry 2005). In contrast to crystalloids, the use of colloids for volume resuscitation may have several advantages. Firstly, colloids containing human albumin have higher SID and are therefore more equal to plasma generating a balance in acid-base chemistry (Roche and James 2009). Moreover, human albumin is associated with an increase in COP and a more positive fluid balance. It even appears that human albumin plays a role in the protection of the EGL integrity (Jacob, Paul et

al. 2009, Becker, Chappell et al. 2010). Despite these potential advantages of human albumin as priming volume in cardiac surgery setting, its cost and its risk for potentially severe anaphylactic reactions are still limitations to its use nowadays (Galvao, Giavina-Bianchi et al. 2014). Likewise, there is conflicting evidence whether the use of synthetic colloid solutions, such as hydroxyethylstarch (HES) or Gelatin/Gelofusine may be beneficial as priming volume for cardiopulmonary bypass in cardiac surgery setting.

This study will provide insight in the role of COP in hemodilution in the perioperative cardiac surgery setting with cardiopulmonary bypass. The aim of this study is to indicate whether there the group that receives albumin or Gelofusine in the predominantly crystalloid prime is beneficial for COP compared to the crystalloid only prime in the CPB circuit.

### Doel van het onderzoek

The addition of albumin or gelofusine in the predominantly crystalloid prime is beneficial for COP compared to the crystalloid only prime in cardiac surgery setting with cardiopulmonary bypass.

### Onderzoeksopzet

Measurements will be performed after induction of anesthesia (T1), after cross-clamping the aorta during CPB (T2), after weaning from CPB (T3) and one hour after weaning from CPB (T4), at arrival on the ICU (T5) and 6 hours after admission on the ICU(T6).
Perioperative and intraoperative characteristics.

### Onderzoeksproduct en/of interventie

Not applicable

## Contactpersonen

### Publiek

Amsterdam UMC, VUmc location
Anne Beukers

0624543517

### Wetenschappelijk

Amsterdam UMC, VUmc location
Anne Beukers

0624543517

# Deelname eisen

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

• Informed consent
• Patients undergoing elective cardiac surgery

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

• Emergency operations
• Patients with previous heart surgery
• Patients undergoing elective thoracic aortic surgery.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-12-2020 |
| Aantal proefpersonen: | 60 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

**Toelichting**
Not applicable

# Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL9055 |
| Ander register | METc VUMC : 2019.343 |

# Resultaten

**Samenvatting resultaten**
Not yet, study is ongoing