Bloodloss study after Aortic valve replacement
Impact of Mecc perfusion vs conventional ECCperfusion

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Peri-operative Bloodloss after Aortic valve replacement

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON39590

Source
ToetsingOnline

Brief title
Bloodloss study after Aortic valve replacement

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
Bloodloss, BloodTransfusion

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Onderzoek wordt niet gefinancierd

Intervention

Keyword: AVR, Bloodloss, ECCperfusion, MECC

Outcome measures

Primary outcome

Lab;C-reactief proteïne, leukocyten, platelets, hemoglobine, hematocriet,

creatinine, ureum, glomerular filtration fate**, CK, CKMB, troponine en

myoglobine

Bloodloss through Thoracicdrains

Amount of bloodtransfusion units

Secondary outcome

Length of stay on ICU

Re-interventions like Re-operatins as a Re-Sternotomia

Study description

Background summary

Every year in the Netherlands about 15,000 patients are undergoing cardiac surgery. An increasing number of these patients are people who are undergoing an aortic valve replacement. By this kind of surgery the use of a heart-lung machine (ECC) is necesary. Thoraxic surgey is associated with blood loss. The use of Heparin, and the heart lung machine can not prevented that there is always some blood loss. However, blood loss, blood transfusion , mortality and morbidity are associated with them. For several years, there is a possibility for using of an MECC system (Minimum extracorporeal Corporal Circulation). This system provides less hemodulutie and tubing contact with the heart-lung machine. The dose of heparin can be reduced. The hypothesis is that with a MECC hart-lungmachine perioperative blood loss can be reduced.

Study objective

Peri-operative Bloodloss after Aortic valve replacement

Study design

RCT

Intervention

Elective Aortic valve replacement

Study burden and risks

Not applicable

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elective indicated AVR procedures

Exclusion criteria

Redo Hartsurgery

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):	01-06-2012
Enrollment:	310
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-12-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL39386.044.12
Other	nummer volgt nog