CONTINUOUS POSTOPERATIVE PERICARDIAL FLUSHING AFTER GENERAL CARDIAC SURGERY PROCEDURES WITH THE HAERMONICS INVESTIGATIONAL DEVICE : STUDY PROTOCOL OF THE FLUID (FLUsh with Investigational Device) TRIAL

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pericardial disorders
Study type	Interventional

Summary

ID

NL-OMON54160

Source
ToetsingOnline

Brief title
The FLUID trial

Condition

- Pericardial disorders
- Therapeutic and nontherapeutic effects (excl toxicity)
- Cardiac therapeutic procedures

Synonym
postoperative hemorage

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Haermonics b.v.,Haermonics b.v. (voorziet in gratis toeleveren van het apparaat) en een EFRO subsidie;Kansen voor West;die 40% van de onderzoekskosten;gemaakt door Amsterdam UMC;vergoedt.

Intervention

Keyword: Cardiac surgical procedures, Chest tubes, Postoperative hemorrhage, Therapeutic irrigation

Outcome measures

Primary outcome

The main study endpoint is the incidence of re-exploration for cardiac

tamponade and/or excessive bleeding due to non-surgical bleeding

Secondary outcome

Blood loss data: Hourly blood loss, Postoperative blood loss after 10-hour

stay in the ICU, Postoperative blood loss at chest tube removal

Hemoglobin * between randomization and 12-hour stay in the ICU (g/dL),

Hemoglobin * between randomization and hospital discharge (g/dL)

Number of units transfused after randomization: Red cells, Fresh-frozen plasma,

Platelet concentrate

Intrapericardial pressure data: CVP during pressure controlled ventilation (5 timepoints within 30 minutes), CVP during pressure support ventilation (5 timepoints within 30 minutes),CVP after extubation (5 timepoints within 30 minutes)

Duration of ventilation, hours

Fluid accumulation at discharge:

postoperative pericardial effusion or pleural effusion

LOS ICU and hospital, days

Cost (measured in consumed care and products)

Time until chest tube removal, hours

Intraluminal chest tube clogging

Adverse events data: Late cardiac tamponade, reoperation (for: surgical bleeding, other reasons), Minimal invasive intervention for fluid accumulation (pericardial intervention, pleural intervention) Infections (sepsis, pneumonia, deep sternal wound infection, surgical wound infection, sternal dehiscence, acute renal insufficiency, postoperative atrial fibrillation, myocardial

infarction, mortality)

Study description

Background summary

Excessive blood loss after open heart surgery is one of the most common causes of complications after thoracic surgery. If excessive blood loss is observed after open surgery, the patient sometimes has to go back to the OR to find the root cause of the bleeding. Sometimes, a clear cause is found and can be solved with an extra stitch, however, often there is a diffuse bloos loss: small bleedings spread in the whole wound bed.

Earlier research has shown that excessive blood loss significantly reduces if the wound bed is irrigated with warm saline directly at the end of the thoracic procedure and the following 12 hours (CPPF). There is less accumulation of blood and clots in the wound.
During studies, blood loss appeared to be reduced signigicantly for those patients treated with continuous postoperative pericardial flushing (CPPF) compared to the standard drainage method. In the CPPF group, no reopoerations were needed, whilst this occured 8 times in the control group. Thhis difference supports the theory that CPPF prevents complications. We can conclude that CPPF is a safe and effective way to reduce blood loss after thoracic surgery.

Study objective

The primary objective of this study is to assess the effects of CPPF, executed by Haermonics Flush, in comparison with standard care on clinically relevant endpoints, like re-explorations, in a population of cardiac surgery patients that have an increased risk for postoperative bleeding. Secondary objectives are to assess the safety and feasibility of a newly developed CPPF device, i.e., the Haermonics Flush, to validate the hct-sensor and to investigate the effect of CPPF on blood loss, coagulation and fibrinolysis. Thirdly, to explore the effect of CPPF therapy on intraluminal chest tube clogging.

Study design

This is a prospective, multicenter, open label, adaptive, randomized clincal trial.

Intervention

One group receives CPPF therapy (inflow of 500 ml NaCl 0,9% flushing fluid into the pericardial cavity during the first 8 postoperative hours) executed with

the Haermonics Flush investigational device) and the other group receives standard care.

Study burden and risks

The extra risk or burden for patients is minimal. Those patients who will be included in the CPPF group, will receive an extra incision for the placement of the inflow tube. An infection as a consequence of this extra incision is a possible complication, however we have not see any evidence for this in earlier studies (about 185 patients flushed).
Remaining infusion fluids is another possible complication; earlier studies have proven that the chance on occluded drains (with the consequence of accumulating blood and fluids in the pericard) is smaller when CPPF is applied. Moreover, in the studies performed so far, no evidence have been found for any residual fluids, also not when patients were scanned radiologically and echographic. On the contrary, there were less interventions for residual blood and fluids in the CPPF group.

The drawing of blood samples will, to our expectance, not increase the risk of the patients included.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults undergoing a general cardiothoracic surgery procedure with the use of cardiopulmonary bypass are eligible for participation

Exclusion criteria

Euroscore II > 20% , Intraoperatively diaphragm injury leading to an open connection between the thoracic and abdominal cavity, Age < 18, Inability to understand study information, Participation in any study involving an investigational drug or device, Emergent procedures, Procedures performed off pump, without the use of cardiopulmonary bypass, Minimal invasive cardiac surgery procedures (e.g. minithoracotomy and hemisternotomy)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2021
Enrollment:	992
Type:	Actual

Medical products/devices used

Generic name:	Pericadial flush device
Registration:	No

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2022
Application type:	Amendment
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Approved WMO Date:	21-02-2023
Application type:	Amendment
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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
ClinicalTrials.gov	NCT05308589
CCMO	NL74428.018.21