Differences in coagulation between fresh frozen plasma and Solvent-detergent plasma in pediatric congenital heart surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28246

Source
NTR

Brief title
FFP-OMNI

Health condition

Congetinal pediatric heart disease

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Dutch Society of Anaesthesiologist (NVA)

Intervention

Outcome measures

Primary outcome

To investigate the differences in coagulation variables just after surgery between FFP and S/D

plasma (Omniplasma) use. The main coagulation variables of interest are protein S activity and α2-antiplasmin. Other important coagulation variables are aPTT, PT, ROTEM, fibrinolysis (measured with ROTEM) fibrinogen, Hb, thrombocyte count, protein C activity, antithrombin and plasminogen.

Secondary outcome

Secondary outcomes are the coagulation variables 24 hours after surgery compared to the pre-operative values and clinical parameters such as perioperative and postoperative blood loss, transfusion need and thrombotic events until 30 days after surgery or until discharge from our hospital. In addition, we also investigate if there are differences in costs between the two products.

Study description

Background summary

Rationale: Fresh frozen plasma (FFP) or quarantine plasma derived from male-only donors was the only plasma product available in the Netherlands till 2013. However, there are some potential risk in using FFP such as transmission of lipid-envelloped viruses and allergic reactions. Therefore many country's has changed their clinical practice and are using solvent-detergent-treated plasma nowadays. In 2013 Sanquin Dutch Blood Supply introduced solvent-detergent-treated (S/D) and pooled plasma named (Omniplasma) in the Netherlands following advice of the Medical advisory board of Sanquin. Omniplasma is a pooled product of around 600 Dutch donors and is S/D treated to destroys the lipid enveloped viruses. In addition there is a prion-reducing step and due to filtration all cells and cell fragments are removed [2]. Since that time Omniplasma is replacing FFP in the Netherlands. However, FFP and S/D plasma are not the same products. In vitro and in vivo studies has shown that S/D plasma is more pro-coagulant, but also more fibrinolytic compared to FFP. Due to the S/D process not only viruses but probably also other proteins, especially the more fragile proteins of the coagulation cascade such as protein S and α2-antiplasmin are destroyed. Therefore the contents of the coagulation factors between the two products are different. However, those studies who investigated the difference between S/D plasma and FFP are performed only in adults not in paediatric cardiac surgery patients.
At the moment during pediatric cardiac surgery, we are still using FFP. However FFP is going to be replaced by Omniplasma. But because the coagulation profile is different between the two products and no data is available in these patient category, we want to perform an implementation study, observing the differences in coagulation between FFP and Omniplasma in pediatric cardiac surgery.

Objective: To investigate differences in coagulation between (Omniplasma) and FFP in paediatric cardiac patients, who are undergoing cardiac surgery.Study design: prospective observational implementation study
Study population: Paediatric patients with congenital heart disease, who needs elective

cardiac surgery with cardiac pulmonary bypass.
Intervention (if applicable): Before and after the replacement of FFP by S/D plasma (Omniplasma) in our department, observational data will be collected during and after cardiac surgery. Together with routine sampling from an indwelling catheter placed under anaesthesia, 3 times 2,7ml blood in 24h hours (shortly before surgery, shortly after and around 24 hours after cardiac surgery) will be taken. The concentration or activity of additional coagulation cascade proteins: protein C activity, protein S activity, antithrombin, α2-antiplasmin and plasminogen will be determined. Blood which is left over after the coagulation factors are determined is not thrown away, but stored for future additional research such as thrombin generation assays. For the study no additional punctures will be performed.

Main study parameters/endpoints: Primary outcome involves the difference of coagulation variables measured just after surgery between FFP or Omniplasma use. The coagulation variables of interest are protein C activity, protein S activity, α2-antiplasmin, antithrombin, plasminogen, Hb, thrombocyte count, ROTEM, aPTT, PT and fibrinogen.
Secondary outcomes are the coagulation variables 24 hours after surgery compared to the pre-operative values and clinical parameters as perioperative and postoperative blood loss, transfusion need, post-operative thrombosis until 30 days after surgery or until discharge from our hospital and costs between the two products.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risk of participating in the study is negligible. All patients will receive standard care. During routine sampling from an indwelling catheter placed during anaesthesia as part of the standard treatment during cardiac surgery, 3 times blood samples will be drawn. The final blood sample will be taken approximately around 24 hours after surgery or just before the catheter is removed. No additional punctures will be done for the study.

Study objective

Omniplasma results in a different concentration in coagulation factors after pediatric congenital cardiac surgery compared to fresh frozen plasma.

Study design

In total, data will be collected of 120 patients. At first the data of 60 patients (30 cardiac surgery patients under 1 years old and 30 cyanotic patients undergoing Glenn or Fontan surgery), still treated with FFP during congenital cardiac surgery, will be collected. Then when all our hospital protocols are changed and the use of Omniplasma is implemented, the data of 60 patients undergoing pediatric cardiac surgery (30 cardiac surgery patients under 1 years old and 30 cyanotic patients undergoing Glenn or Fontan surgery) treated with Omniplasma, will be collected again.
After induction of general anesthesia and placement of intravenous, arterial and central venous lines, blood will be collected for routine laboratory tests such as Hb, thrombocytes, ROTEM, aPTT, PT. In addition protein C activity, protein S activity, antithrombin, α2-antiplasmin and plasminogen will be determined.

After surgery the patient will be transported to the Cardiac Thoracic ICU to stabilize. When patient is stabilized and most transfusion requirements are done, protein C activity, protein S activity, antithrombin, α2-antiplasmin and plasminogen are again determined, besides the routine laboratorial tests such as: Hb, thrombocytes, fibrinogen, ROTEM, aPTT, PT.
24 hours after surgery for the last time blood for routine laboratory a.o. Hb and thrombocyt count, aPTT, PT, fibrinogen and antithrombin, α2-antiplasmin and protein C activity, protein S activity and plasminogen are collected.

Intervention

3 times coagulation factors determination (prior surgery, just after surgery and 24 ours after surgery)

Contacts

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Eligibility criteria

Inclusion criteria

· Informed consent
· Cardiac surgery with the use of CPB
· Group 1A and Group 2A children < 1 year old
· Group 1B and Group 2B Glenn / Fontan surgery

Exclusion criteria

· No informed consent
· Cardiac surgery without the use of CPB
· Preoperative known coagulation disorders

· Known allergy for FFP or Omniplasma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2021
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	04-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51227
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9515
CCMO	NL75930.078.21
OMON	NL-OMON51227

Study results