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

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This study has been transitioned to CTIS with ID 2024-514073-22-01 check the CTIS register for the current data. To investigate differences in coagulation between (Omniplasma) and FFP in paediatric cardiac patients, who are undergoing cardiac...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational non invasive

Summary

ID

NL-OMON51227

Source
ToetsingOnline

Brief title
FFP-Omni

Condition

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

Synonym
bloedstolling, coagulation, congenitale cardiac surgery

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie
Source(s) of monetary or material Support: Ministerie van OC&W,NVA cardiologie sectie

Intervention

Keyword: coagulation, congenital heart surgery, fresh frozen plasma, Solvent-detergent plasma

Outcome measures

Primary outcome

Primary outcome involves the difference of coagulation variables between

transfusion of FFP versus Omniplasma. Coagulation variables of interest are

protein C activity, protein S activity, α2-antiplasmin, antithrombin,

plasminogen, Hb, thrombocyte count, ROTEM, aPTT, PT and fibrinogen.

Secondary outcome

Secondary outcomes are 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.

Study description

Background summary

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.

Study objective

This study has been transitioned to CTIS with ID 2024-514073-22-01 check the CTIS register for the current data.

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 burden and risks

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.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns

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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2021
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Omniplasma
Generic name:	Omniplasma
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-03-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	07-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	04-03-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-03-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28246
Source: NTR
Title:

In other registers

Register	ID
EU-CTR	CTIS2024-514073-22-01
EudraCT	EUCTR2021-000444-22-NL
CCMO	NL75930.078.21
OMON	NL-OMON28246