

# Intervention pilot with fibrinogen concentrate and the combination of fibrinogen concentrate with FFP in patients with massive post/peri-operative bleeding problems

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24904

### Source

Nationaal Trial Register

### Brief title

Intervention pilot with fibrinogen concentrate

### Health condition

general surgery patients, heart valve replacement, peri/post operative bleeding problems  
algemene chirurgie patiënten, hartklep vervanging, peri/post operatieve bloedingsproblemen

## Sponsors and support

**Primary sponsor:** dr. JWM. Heemskerk

P.I. CARIM

**Source(s) of monetary or material Support:** University of Maastricht, initiator  
1st and 3rd funding

## Intervention

## Outcome measures

### Primary outcome

Stop of bleeding after the therapy. The clinical situation after the treatment will be compared with conventional coagulation tests (aPTT, PT, fibrinogen level).

### Secondary outcome

Thrombin generation and thromboelastography measurements, measured with the CAT en TEG method.

## Study description

### Background summary

Patients with post/peri operative bleeding problems usually are transfused with 4 units of FFP, unfortunately this leads to dilutional coagulopathy due to the dilution effect of the transfusion itself. The administration of factor concentrates, especially fibrinogen, consists of only a small bolus injection. There is no dilution effect of this latter treatment, no dilutional coagulopathy will occur. Briefly, fibrinogen concentrates with FFP (only 2 units) together will be a better alternative in bleeding problems than the current 4 units of FFP.

### Study objective

The combination of fibrinogen concentrate with FFP transfusion to patients with massive post/peri-operative bleeding problems is a better alternative than FFP transfusion alone, due to the prevention of dilutional coagulopathy.

### Study design

Before and after the given therapy

### Intervention

Comparing FFP transfusion in massive bleeding patients with the combination of fibrinogen and FFP/DDAVP

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. General surgery patients with massive peri-operative bloodloss, with an indication of receiving 4 units of FFP according to current guidelines.
2. Cardiothoracic surgery patients after heart valve replacement who met the criteria of increased bloodloss and indication for DDAVP.

### Exclusion criteria

1. No other therapeutical anti-thrombotica are given, other than platelet-aggregation inhibitors
2. Patients with active HIV-infection
3. Patients who received FFP or fibrinogen just before the surgery
4. Patients who are hypotherm ( $< 30^{\circ}\text{C}$ ) or with a circulatory arrest

5. Patients with a fibrinogenlevel > 2 g/L

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	100
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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
NTR-new	NL1173
NTR-old	NTR1218
Other	Transfusion policy :
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

Main resource:<br>

Mittermayr M et al. Hemostatic changes after crystalloid or colloid fluid administration during major orthopedic surgery:the role of fibrinogen administration. Anesth Analg. 2007; 105