Intervention pilot study with FFP or the combination of fibrinogen concentrate and FFP to patients with massive (post) operative bloodloss.

Published: 07-07-2008
Last updated: 06-05-2024

In this study we will try to obtain the rise in value of fibrinogen concentrate infusion in combination with FFP vs FFP transfusion in surgery patients with massive peri-operative bleeding problems and cardiothoracic surgery patients after heart...

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

Summary

ID

NL-OMON31952

Source
ToetsingOnline

Brief title
Intervention pilot study with fibrinogen concentrate

Condition

- Other condition

Synonym
transfusion policy and coagulation in case of massive bleeding

Health condition

Stollingsstoornissen/massaal bloedverlies

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,bedrijven zie G2a.,CSL Behring, Marburg

Intervention

Keyword: FFP, fibrinogen concentrate, massive bleeding, pilot study

Outcome measures

Primary outcome

Primary study parameters are the amount of blood loss and the use of blood

products.

Secondary outcome

Thrombin generation measurements and thromboelastograhy will be compared with

conventional coagulation tests.

Study description

Background summary

Treatment of patients with massive bleeding upon surgery cosists of infusion of cristalloids, colloids, thrombocyte-concentrates and erythrocyte-concentrates. Additionally fresh frozen plasma (FFP) will be transfused, this FFP is diluted with anticoagulans and therefore FFP has a lower concentration of coagulation factors in comparison with undiluted plasma.
Because of the fact that these patients are treated with a combination of the above mentioned infusion fluids, an important dilution of coagulation factors will occur together with the coagulation ability of plasma of these patients. The dilution is only partly compensated by FFP transfusion, and as a consequence part of the patients will continue bleeding due to insufficient coagulation capacity. There is an increased interest for treatment of these acquired coagulation disorders with coagulation factor concentrates. Fibrinogen, which is involved in the clot formation, is the first coagulation factor that will be deficit in case of massive bleeding and dilution.

Study objective

In this study we will try to obtain the rise in value of fibrinogen concentrate infusion in combination with FFP vs FFP transfusion in surgery patients with massive peri-operative bleeding problems and cardiothoracic surgery patients after heart valve replacement with massive post-operative bleeding problems. The administration of fibrinogen concentrate (besides the FFP) can cause stop of bleeding in an earlier phase, so that the total amount of bloodtransfusion will be reduced. The recovery after surgery will be influenced positively. Furhtermore the advantages of new laboratory tests to determine coagulation ability and fibrin clot formation, will be studied and compared with conventional coagulation times (insensitive for measurements of current hemostasis) in favour of future transfusion policy.

Study design

Potential patients will be asked for informed consent before surgery, general surgery patients with massive bloodloss during surgery will be randomised between FFP and a lower dosage of FFP with fibrinogen concentrate. Cardiothoracic surgery patients after heart valve surgery with massive post-operative bleeding problems will be randomised between DDAVP and fibrinogen concentrate. During the study 5 cc citrate blood will be taken twice from each patient extra, however patients do not need to undergo an extra invasive procedure.

Intervention

DDAVP injection (standard therapy of cardiothoracic patients with massive post-operative bleeding problems) vs. an combination of DDAVP with fibrinogen concentrate.
FFP transfusion (standard therapy of general surgery patients with massive peri-operative bleeding problems) vs. an combination of a lower dosage of FFP with fibrinogen concentrate.

Study burden and risks

To obtain the extra tube of blood before and after the intervention, a patient does not need to undergo an extra invase procedure, because at these time points blood is taken anyway. The additonal amount of blood is needed to determine additional coagulation factor concentrations, thrombin generation and thromboelastography. The injection of fibrinogen occurs in small volumes after which the treatment effect will appear immediately. In this way no time is lost for the standard therapy to be given when there is no effect of the fibrinogen concentrate.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
6229 ER Maastricht
Nederland
Scientific
Universiteit Maastricht

Universiteitssingel 50
6229 ER Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with massive bloodloss during surgery and coagulopathy, who are transfused with FFP according to actual guidelines. Cardiothoracic surgery patients after heart valve replacement with massive bloodloss after surgery.

Exclusion criteria

No therapeutic anticoagulans other than inhibitors of platelet aggregation.
Patients with active HIV-infection
Patients received FFP or fibrinogen before the surgery
Patient without informed consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	09-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL23565.068.08
Other	www.trailregister.nl 1218