The Tranexaminic acid - Aprotinin - Placebo trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25344

Source
Nationaal Trial Register

Brief title
TAP Trial

Health condition

Intra-operative medication trial.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: local

Intervention

Outcome measures

Primary outcome

1. Intraoperative and perioperative blood loss;

2. Intraoperative and perioperative use of blood products.

Secondary outcome

1. Rethoracotomies;

2. The total duration of each patient's stay in the operating room;

3. Length of stay in the ICU and hospital;

4. Development of SIRS/sepsis/MOF;

5. 30-day morbidity;

6. 30-day mortality;

7. Costs.

Study description

Background summary

Bleeding and the need foor blood transfusions are correlated with increased morbidity, mortality and higher costs. Aprotinin and tranexamic acid have shown to reduce borh blood loss and transfusion requirements during and after cardiac surgery. The efficacy and cost effectivity of tranexamic acid in comparison to aprotinin has been minimally investigated. The few controlled clinical trials that have been performed show a slight benefit of aprotinin over tranexamic acid.

The purpose of this study is to determine which of these pharmacological agents is most efficious and cost effective compared to standard treatment.

Study objective

We expect that aprotinin will be better in reducing blood loss and transfusion requirements compared with tranexamic acid. However, tranexamic acid will be more cost effective and avoid the risk of anaphylactic shock at reexposeure seen with aprotinin.

Study design

N/A

Intervention

Group A will receive placebo;

Group B will receive high dose aprotinin;

Group C will receive tranexamic acid.

- All medications will be administered during surgery. Anesthetic and surgical procedures in all groups will be carried out according to standard care ;
- All patients will be observed until their discharge, during which time all measurements obtained during standard care will be recorded;

- One blood monster preoperative and four blood monsters will be taken postoperatively to asses for protein concentrations related to SIRS.

Contacts

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Eligibility criteria

Inclusion criteria

Patients scheduled for first time, non-complex (one or two procedures) open heart surgery with the use of CPB.

Exclusion criteria

1. Less than 18 years old;

2. Previous sternotomy;

3. Previous aprotinin therapy;

4. Known or suspected allergy to aprotinin;

5. Refusal to receive blood transfusion;

6. Abnormal perioperative coagulation profile for reasons other than anticoagulant therapy;

7. Treatment with antiplatelet agents within the 5 days before the operation;

8. Known bleeding disorder;

9. Pregnancy;

10. Scheduled for 3 or more procedures;

11. Emergency operations.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2004
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	07-09-2005
Application type:	First submission

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	NL224
NTR-old	NTR261
Other	: N/A
ISRCTN	ISRCTN00157697

Study results

Summary results
N/A