

The clinical and economic effectiveness of high-dose aprotinin and tranexamic acid in patients undergoing first time open-heart surgery: a single-centre, double blind, prospective, randomised, placebo-controlled trial

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/08/2009	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR261

Study information

Scientific Title

Acronym

TAP Trial: Tranexaminic acid - Aprotinin - Placebo trial

Study objectives

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 reexposure seen with aprotinin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart surgery, Cardiopulmonary Bypass (CPB), bleeding

Interventions

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 sample preoperative and four blood samples will be taken postoperatively to assess for protein concentrations related to Systemic Inflammatory Response Syndrome (SIRS).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aprotinin, tranexaminic acid

Primary outcome(s)

1. Intraoperative and perioperative blood loss
2. Intraoperative and perioperative use of blood products

Key secondary outcome(s)

1. Rethoracotomies
2. The total duration of each patient's stay in the operating room
3. Length of stay in the Intensive Care Unit (ICU) and hospital
4. Development of SIRS/sepsis/Multiple Organ Failure (MOF)
5. 30-day morbidity
6. 30-day mortality
7. Costs

Completion date

31/08/2006

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key 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 five days of the operation
8. Known bleeding disorder
9. Pregnancy
10. Scheduled for three or more procedures
11. Emergency operations

Date of first enrolment

31/05/2004

Date of final enrolment

31/08/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No