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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
31/05/2004

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

Age group
Adult

Sex
Both

Target number of participants

300

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)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type

University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leiden University Medical Centre (LUMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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