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Evaluation of Haemate HS for the treatment of severe intraoperative hemorrhage during aortic-valve replacement in patients with aortic-valve stenosis

Submission date
07/12/2007

Recruitment status
No longer recruiting

Registration date
08/02/2008

Overall study status
Completed

Last Edited
08/02/2008

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
BI8021_5101

Study information

Scientific Title

Acronym
HAVAS-Study

Study objectives
Evaluation of the efficacy and safety of Haemate HS in this clinical setting

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Committee of the Heinrich Heine University Medical Center (Duesseldorf, Germany) on 25 April 2007. First amendment approved on 28 November 2007.

Study design
Two-arm, randomised, double-blind controlled clinical study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe intraoperative hemorrhage during aortic-valve replacement

Interventions
Intervention group: Intraoperative infusion Haemate HS 500/1000 IU (vWF/F VIII:C concentrate), time of infusion according to inclusion criteria.
Control group: Intravenous infusion of 0.9% NaCl solution (100 ml)

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Haemate HS (intraoperative infusion)

Primary outcome measure
Intra- and postoperative transfusion requirements according to defined transfusion thresholds.

Secondary outcome measures
1. Requirement of rethoracotomy, assessed during patients stay at the intensive care unit
2. Surgeons' subjective rating of therapeutic efficacy after application of Haemate HS or placebo (classification of bleeding after therapy as "better", "equal" or "worse")
3. Survival (perioperative mortality, mortality during hospital stay, mortality within a 90 day period following surgery)
4. Duration of treatment on intensive care ward
5. Adverse events and therapy-related side effects, assessed within the first 10 days after surgery. A second assessment is carried out after 3 month (at day 90)

Overall study start date
19/10/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients with isolated valvular aortic stenosis or combined aortic-valve defect with prevailing stenosis (mean transvalvular gradient >50 mmHg) with severe bleeding during aortic-valve replacement
2. Age >18 years.
3. Written informed consent.
4. All patients that fulfill at least one of the following criteria 15 minutes after the end of extracorporal circulation and application of protamine:
4.1. Excessive bleeding without surgical explanation according to the surgeons' impression (Classification of bleeding as "normal", "moderate" or "excessive" by the surgeon. Classification as "excessive" bleeding leads to recruitment to the study).
4.2. Drainage volume >40 ml in 5 minutes following application of protamine and thorax closure.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 patients (20 per arm)

Key exclusion criteria
1. Participation in other interventional studies that potentially impair the interpretation of results
2. History suggestive for inherited or acquired bleeding disorder
3. Written informed consent not to be obtained
4. Active endocarditis
5. Concomitant coronary heart disease
6. Agents impairing platelet function at the time of surgery
7. Pregnancy
8. Known or suspected intolerance against Haemate HS
9. Previous thromboembolic complications
10. Known hepatitis B, hepatitis C or HIV infection
11. Known or suspected intolerance against standard medication (e.g., heparin)
12. Emergency surgery within the last 7 days
13. Previous chemotherapy

Date of first enrolment
19/10/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Department of Hemostasis and Transfusion Medicine
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Sponsor information

Organisation
Heinrich Heine University Duesseldorf (Germany)

Sponsor details

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Sponsor type
Not defined

ROR
https://ror.org/024z2rq82

Funder(s)

Funder type
Industry

Funder Name
CSL Behring GmbH (Germany)

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