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The effectiveness of various groups of 24-hour tranexamic acid treatment in the prevention of systemic inflammatory response syndrome and post-operative bleeding in elective cardiopulmonary bypass patients

Submission date
10/06/2009

Recruitment status
No longer recruiting

Registration date
15/07/2009

Overall study status
Completed

Last Edited
05/04/2012

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
2004-001366-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TX/05 v.2; EudraCT: 2004-001366-41

Study information

Scientific Title
Randomised double-blind phase IV clinical trial on 24 hours duration of various groups of tranexamic acid treatment on the effectiveness in the prevention of systemic inflammatory response syndrome and post-operative bleeding in elective cardiopulmonary bypass patients

Study objectives
Hyperfibrinolysis may play a role in systemic inflammatory response syndrome (SIRS) after cardiopulmonary bypass (CPB). Irregular inhibition of fibrinolysis with different doses of tranexamic acid may attenuate unequally SIRS after CPB.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local medical ethics committee (Comite Etico de Investigacion Clinica del Hospital Universitario De Canarias) approved on the 1st March 2005

Study design
Randomised double-blind phase IV clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Systemic inflammatory response syndrome (SIRS), post-operative bleeding

Interventions
Patients were randomly assigned by independent pharmacists using a list of pseudo-randomised numbers to receive coded infusions of either tranexamic acid (TA) (40 mg/kg pre-CPB and 40 mg /kg post-CPB) or TA (40 mg/kg pre-CPB and 0 mg/kg post-CPB) after protamine administration.

Patients were followed-up from the first 24 hours after surgery up to ICU discharge.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Tranexamic acid, protamine

Primary outcome measure
Biochemical determinations and haemodynamics parameters, recorded before intervention (baseline), on admission to the ICU after surgery (0 hours), and at 4 hours, 12 hours and 24 hours after surgery

Secondary outcome measures
1. Blood loss, measured by tube chest drainage and the amount of haemoderivatives used, as well as its frequency, collected after intervention on admission to the ICU after surgery (0 hours), and at 4 hours, 12 hours and 24 hours after surgery, and when chest tubes were removed
2. Mortality, measured from the first 24 hours after surgery up to ICU discharge
3. Mechanical ventilation time, measured from the first 24 hours after surgery up to ICU discharge
4. Vasopressor requirements, measured from the first 24 hours after surgery up to ICU discharge
5. ICU length of stay, measured from the first 24 hours after surgery up to ICU discharge

Overall study start date
01/12/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Equal or older than 18 years old, either sex
2. Elective cardiopulmonary bypass surgery
3. Informed consent approval

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Younger than 18 years old
2. Tranexamic acid hypersensibility
3. Gross haematuria
4. Emergency interventions
5. Off-pump cardiac surgery
6. Patients with a history of:
6.1. Chronic coagulopathy (prothrombin time [PT] of less than 50% or international normalised ratio of greater than 2 and platelets of less than 50,000/mm^3 or aggregation dysfunction)
6.2. Renal failure (creatinine of greater than 2 mg/dl)
6.3. Chronic hepatopathy (Child B or higher degree)
6.4. Use of immunosuppressant drugs
6.5. Endocarditis, sepsis in the first 24 hours after intervention, or
6.6. Unwillingness to enrol
6.7. Use of anti-inflammatory agents such as corticosteroids or non-steroidal anti-inflammatory agents, on the previous 5 days before intervention

Date of first enrolment
01/12/2005

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Spain

Study participating centre
Ofra s/n. La Cuesta
La Laguna
Spain
38320

Sponsor information

Organisation
Hospital Universitario de Canarias (Spain)

Sponsor details
Ofra s/n. La Cuesta
La Laguna

S.C. Tenerife
Spain
38320

Sponsor type
Hospital/treatment centre

Website
http://www.huc.es

ROR
https://ror.org/05qndj312

Funder(s)

Funder type
Research organisation

Funder Name
Canary Islands Foundation of Health Research (Fundación Canaria de Investigación y Salud [FUNCIS]) (Spain) (ref: 48/04)

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	14/10/2011		Yes	No