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	Recruitment status No longer recruiting	Prospectively registered	
10/06/2009		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
15/07/2009	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
05/04/2012	Injury, Occupational Diseases, Poisoning		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Juan Jose Jimenez

Contact details

Ofra s/n. La Cuesta La Laguna Spain 38320 jjjimenezrivera@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS) 2004-001366-41

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes