

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

☐ Prospectively registered

☐ Protocol

Registration date

15/07/2009

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/04/2012

Condition category

Injury, Occupational Diseases, Poisoning

☐ 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 hypersensitivity
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/mm³ 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