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Randomised, double-blind, controlled study of the tranexamic acid prophylaxis efficacy on the development of systemic inflammatory response syndrome and postoperative bleeding in cardiopulmonary bypass surgery patients

Submission date 21/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/05/2007	**Overall study status** Completed	
Last Edited 05/01/2021	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Tranexamico/2002

Study information

Scientific Title

Randomised, double-blind, controlled study of the tranexamic acid prophylaxis efficacy on the development of systemic inflammatory response syndrome and postoperative bleeding in cardiopulmonary bypass surgery patients

Acronym
TX/02

Study objectives
We hypothesised that the inhibition of fibrinolysis through the administration of tranexamic acid could reduce the incidence of systemic inflammatory response syndrome and postoperative bleeding after cardiopulmonary bypass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the University Hospital of Canary Islands Ethics and Research Council on the 20th December 2001 (ref: 35/01).

Study design
Randomised, double-blind, controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Systemic inflammatory response syndrome

Interventions
Infusions of either tranexamic acid or placebo (0.9% saline), with doses of 2 g pre- and post-cardiopulmonary bypass after protamine administration.

Follow-up continued until the patient was discharged from the hospital.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)
To investigate the efficacy of tranexamic acid in decreasing the incidence of systemic inflammatory response syndrome and postoperative bleeding.

Data was recorded preoperatively, after surgery, at Intensive Care Unit admission (0 hours), four hours and 24 hours.

Key secondary outcome(s))
To investigate the efficacy of tranexamic acid to reduce excessive postoperative bleeding in patients undergoing cardiac surgery, according to the presence of different genotypes of the Plasminogen Activator Inhibitor (PAI-1) gene.

Data was recorded preoperatively, after surgery, at Intensive Care Unit admission (0 hours), four hours and 24 hours.

Completion date
01/09/2003

Eligibility

Key inclusion criteria
Consecutive Caucasian adults undergoing elective cardiopulmonary bypass surgery with normal aggregation and coagulation test values.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Emergency interventions
2. Patients with a history of haemostatic dysfunction
3. Renal failure (creatinine greater than 2 mg/dl)
4. Chronic hepatopathy
5. Immunodepressed patients
6. Sepsis

Date of first enrolment
01/06/2002

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
Spain

Study participating centre
Ofra s/n
La Laguna
Spain
38320

Sponsor information

Organisation
University Hospital of Canary Islands (Consorcio Sanitario de Tenerife [CST]) (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: 2202)

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	01/08/2007	05/01/2021	Yes	No