ISRCTN58678663 https://doi.org/10.1186/ISRCTN58678663

The anti-endotoxin agent, taurolidine, potentially reduces ischaemia-reperfusion injury through its metabolite taurine

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/07/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/07/2009	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An investigation into the efficacy of the anti-endotoxin agent, taurolidine in the attenuation of the post-reperfusion sequelae in patients subjected to cardio-pulmonary bypass: a double-blinded randomised clinical trial

Study objectives
Peri-operative administration of taurolidine decreases inflammatory response to cardiopulmonary bypass (CPB) and attenuates ischaemia-reperfusion (I-R) injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University College Cork (Ireland) granted approval on the 5th March 1999, as well as the Irish Medicines Board (IMB)

Study design
Double-blinded randomised controlled 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
Ischaemia-reperfusion injury

Interventions
From induction of anaesthesia, patients were administered 250 ml of 2% taurolidine or normal saline twice daily intravenously for 3 doses in total.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Taurolidine

Primary outcome measure
Cytokines interleukin-6 (IL-6) and interleukin-10 (IL-10), measured immediately pre-operatively, at aortic unclamping, two, six and 24-hours post-unclamping

Secondary outcome measures
1. CD11b and CD14 receptor expression, measured immediately pre-operatively, at aortic unclamping, two, six and 24-hours post-unclamping
2. Respiratory burst and phagocytosis of circulating neutrophils, measured immediately pre-operatively, at aortic unclamping, two, six and 24-hours post-unclamping
3. Plasma lipopolysaccharide (LPS), measured immediately pre-operatively, at aortic unclamping, two, six and 24-hours post-unclamping
4. Arrhythmias, analysed intra-operatively and daily up until hospital discharge
5. Complications, analysed intra-operatively and daily up until hospital discharge

Overall study start date
01/01/1999

Completion date
31/12/2001

Eligibility

Key inclusion criteria
1. Patients (aged greater than or equal to 18 years, either sex) undergoing elective coronary artery bypass grafting
2. Left ventricular ejection fraction greater than 30% (affects likelihood of developing infection post-operatively for various reasons including increased inotropic support requirements, longer intensive care unit [ICU] stay, delayed mobilisation, and delayed removal of urinary catheters and intravenous lines)
3. Normal pulmonary function tests (affects likelihood of developing respiratory complications post-operatively)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients with diabetes mellitus (affects likelihood of developing infection post-operatively)
2. Patients taking angiotensin-converting enzyme inhibitors (affects potential to reduce reperfusion injury by acting on leukocytes)
3. Patients taking steroids (more prone to developing infection)
4. Patients with chronic arrhythmias

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/2001

Locations

Countries of recruitment
Ireland

Study participating centre
Department of Surgery
Cork
Ireland
-

Sponsor information

Organisation
Cork University Hospital (Ireland)

Sponsor details
c/o Professor H.P. Redmond
Department of Academic Surgery
University College Cork
Cork
Ireland
-

Sponsor type
Hospital/treatment centre

Website
http://www.ucc.ie/en/

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cork University Hospital (Ireland) - Department of Academic Surgery, University College Cork

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