ISRCTN42445141 https://doi.org/10.1186/ISRCTN42445141

Prospective, randomised trial comparing fluids and dobutamine optimisation of oxygen delivery in high-risk surgical patients

Submission date
27/03/2006

Recruitment status
No longer recruiting

Registration date
30/03/2006

Overall study status
Completed

Last Edited
26/03/2008

Condition category
Circulatory System

[_] 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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15091/000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2611/2002

Study information

Scientific Title

Study objectives
We aimed to investigate the effect of oxygen delivery index (DO2I) optimisation with fluids versus with fluids and dobutamine on 60-day hospital mortality and incidence of complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics board on the 13th May 2002 (ref: 2611 /2002).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
High-risk patients undergoing prolonged surgery

Interventions
Therapy consisted of pulmonary artery catheter (PAC)-guided haemodynamic optimisation during the operation and 24 hours postoperatively, using either fluids alone or fluids and dobutamine with the aim of achieving supranormal values (oxygen delivery index [DO2I] greater than 600 ml/min/m^2).

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
To evaluate the effect of both DO2I optimisation with fluids compared to with fluids and dobutamine on 60-day mortality in high-risk general surgery patients.

Secondary outcome measures
The incidence of complications, particularly adverse cardiovascular events.

Overall study start date
13/05/2002

Completion date
31/05/2004

Eligibility

Key inclusion criteria
Patients older than 18 years old undergoing elective surgeries with greater than or equal to three points according to a risk scoring system adapted from the American College of Cardiology (ACC) or the American Heart Association (AHA) guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

Key exclusion criteria
1. Refusal of consent
2. Haemodynamic instability prior to surgery
3. Congestive heart failure
4. Presence of infection
5. Acute myocardial ischaemia prior to enrolment
6. Life expectancy lower than 60 days
7. Disseminated malignancy

Date of first enrolment
13/05/2002

Date of final enrolment
31/05/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Av Faria Lima 5416
São Paulo
Brazil
15091/000

Sponsor information

Organisation
Faculty of Medicine of São José do Rio Preto (FAMERP) Foundation (Brazil)

Sponsor details
Av. Brigadeiro Faria Lima, 5416
Vila São Pedro
São Paulo
Brazil
15091/000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052e6h087

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Faculty of Medicine of Sao Jose do Rio Preto Foundation (Fundacao Faculdade de Medicina de Sao Jose do Rio Preto [FAMERP] - Hospital de Base) (Brazil)

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	01/07/2006		Yes	No