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Effects of "Restrictive" and "Liberal" strategies of intra-operative fluid management during optimisation of oxygen delivery in high-risk surgical patients

Submission date 02/07/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/09/2007	**Overall study status** Completed	
Last Edited 31/12/2020	**Condition category** Surgery	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
Effects of "Restrictive" and "Liberal" strategies of intra-operative fluid management during optimisation of oxygen delivery in high-risk surgical patients

Acronym
RxL

Study objectives
"Restrictive" strategy for fluid administration has been shown to improve outcomes in certain groups of surgical patients. Whether a "restrictive" strategy can be used safely in high-risk patients using dobutamine to optimise cardiac function is not known.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee (Comite de Etica em pesquisa da Faculdade de Medicina de Sao Jose do Rio Preto) on the 20th January 2006 (ref: 4361/2005).

Study design
Prospective 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
Oxygen delivery in high-risk surgery

Interventions
Lithium indicator dilution and pulse power analysis is used to measure cardiac output and to calculate Oxygen Delivery Index (DO2I) (LiDCO-plus system). A goal-directed therapy is used during surgery and eight-hours post-operatively aiming to maximise DO2I to levels higher than 600 ml/min/m^2 using dobutamine and either "restrictive" (4 ml/kg/min) or "liberal" (12 ml/kg /min) strategies of intra-operative fluid management. Post-operatively both groups received 1.5 ml/kg/min of lactated ringer. Fluid challenge with 250 ml of colloid is given if there are signs of hypovolaemia.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Post-operative complications and hospital/Intensive Care Unit (ICU) length of stay.

Primary and secondary outcomes will be measured during the first interim analysis planned that will probably be done in around 2 months (according to the number planned in the project).

Secondary outcome measures
1. Perfusion variables (serum lactate, central venous oxygen saturation)
2. Organ dysfunction

Primary and secondary outcomes will be measured during the first interim analysis planned that will probably be done in around 2 months (according to the number planned in the project).

Overall study start date
20/02/2006

Completion date
20/02/2008

Eligibility

Key inclusion criteria
1. Adult patients
2. Either major surgery and one clinical predictor of risk or intermediate risk surgery and the association of two clinical predictors (scoring system adapted from Shoemaker criteria/American College of Cardiology [ACC]/American Heart Association [AHA])

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
116 patients (58 in each group). First analysis on 50% of the patients enrolled.

Total final enrolment
88

Key exclusion criteria
1. Emergency surgery
2. Acute myocardial ischaemia less than one month
3. Congestive heart failure (Functional Class IV New York Heart Association [NYHA])
4. Chronic renal failure (pre-operative creatinine greater than 2.0 mg/dl or need for dialysis)
5. Patients on lithium therapy
6. Severe arrhythmia

Date of first enrolment
20/02/2006

Date of final enrolment
20/02/2008

Locations

Countries of recruitment
Brazil

Study participating centre
Av Faria Lima 5544
São José do Rio Preto
Brazil
15090-000

Sponsor information

Organisation
Faculty of Medicine of Sao Jose do Rio Preto (FAMERP) Foundation (Brazil)

Sponsor details
Centro de Estudos e Pesquisa em Terapia Intensiva do Hospital de Base
c/o Professor Suzana Lobo
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Sponsor type
Hospital/treatment centre

Website
http://www.famerp.br/

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	01/09/2011	31/12/2020	Yes	No