

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

<b>Submission date</b> 27/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/03/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Suzana Lobo

### Contact details

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São Paulo  
Brazil  
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<sup>2</sup>).

## 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?
<a href="#">Results article</a>	Results	01/07/2006		Yes	No