

Efficacy of intraoperative optimisation of fluids guided with transoesophageal doppler monitorisation

Submission date 18/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/02/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/12/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
ECRYCHIL18012011CQ

Study information

Scientific Title
Efficacy of intraoperative optimisation of fluids guided with transoesophageal doppler monitorisation: a multicentre randomised controlled trial

Study objectives

The intraoperative optimisation of fluids guided with transoesophageal doppler monitorisation allows a decrease in the morbidity rate and resources consumption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

High risk surgical procedures under general anaesthesia

Interventions

Intervention group: transoesophageal doppler monitorisation

Control group: conventional monitorisation

The intervention group consists of cardiovascular continuous oesophageal Doppler monitoring during the surgical intervention, while in the control group the cardiovascular function is estimated measuring a series of haemodynamic-related variables such as arterial pressure, temperature or diuresis.

The follow up of both arms are observed until the hospital discharge for short term outcomes and by a clinical records review until the sixth month after the hospital discharge for long term outcomes.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Post-operative short term complications

Key secondary outcome(s)

Measured all along the hospital stay:

1. Hospital length of stay
2. Morbidity and mortality, also measured at the sixth month after hospital discharge

Completion date

31/12/2011

Eligibility

Key inclusion criteria

1. Patient is under general anaesthesia
2. Major surgery with more than 2 hours
3. Estimated volume loss superior to 15% of volemia
4. Procedure with estimated transfusion need of 2 units of blood substitute
5. High risk surgical procedures in urology, gynaecology, abdominal surgery and traumatology
6. Aged 18 years or over, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

450

Key exclusion criteria

1. Patient aged less than 18 years
2. High risk surgical procedures with unforeseen complications
3. Severe bleeding
4. Nasal or facial trauma
5. Trauma preventing proper insertion of the product (probe)
6. Oesophageal anomalies such as stenosis, oesophageal varices with risk of rupture, severe oesophagitis
7. Oesophageal stents
8. Oesophageal tumour
9. Surgery at the level of the oesophagus or upper airway
10. Pneumo a/o cardiopathy that needs treatment before surgery
11. American Society of Anaesthesiology (ASA) grade IV - V

Date of first enrolment

01/01/2011

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

Spain

Study participating centre

Calle Gran via del Este N°80

Madrid

Spain

28031

Sponsor information

Organisation

Deltex Medical Ltd (Spain)

ROR

<https://ror.org/02skfv902>

Funder(s)

Funder type

Industry

Funder Name

Deltex Medical Ltd (Spain)

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	01/04/2018	18/12/2020	Yes	No