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Efficacy of intraoperatory optimisation of fluids guided with transoesophageal doppler monitorisation

Submission date	Recruitment status	[_] Prospectively registered
18/01/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/02/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2020	Surgery	

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 intraoperatory optimisation of fluids guided with transoesophageal doppler monitorisation: a multicentre randomised controlled trial

Study objectives

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

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 traumalogy
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 Nº80
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