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Esophageal Doppler guided fluid management Improves blood lactate clearance in multiple Trauma Patients: a randomised controlled trial

Submission date
03/10/2006

Recruitment status
No longer recruiting

Registration date
19/10/2006

Overall study status
Completed

Last Edited
26/04/2007

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
EDITP

Study objectives
Early optimisation of intravascular volume using esophageal Doppler in comparison with standard haemodynamic management may in multiple trauma patients improve blood lactate clearance and reduce organ dysfunction development.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Local Research Ethics Committee of University Hospital in Plzen on 10/05/2002.

Study design
Interventional open 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
Multiple trauma patients

Interventions
Patients were randomised into protocol or control group according to the assigned admission number generated by admission office of hospital.

Fluid management in control group patients was managed using routine cardiovascular and clinical monitoring. Fluid resuscitation of protocol group patients was guided for first 12 hours of ICU stay according to the protocol based on data obtained by esophageal Doppler. After 12 hours the esophageal probe was removed and following fluid management in both groups was guided in the same way as in control group.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Blood lactate clearance after 12 and 24 hours after ICU admission
2. Organ dysfunction development during ICU stay

Secondary outcome measures
1. Duration of ICU and hospital stay
2. The incidence of infectious complications during ICU stay

Overall study start date
01/03/2003

Completion date
25/10/2005

Eligibility

Key inclusion criteria
Ventilated patients with multiple trauma and estimated blood loss more than 2000 ml admitted to interdisciplinary Intensive Care Unit (ICU) of teaching university hospital in 2003 to 2005.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Target number of participants was 160

Key exclusion criteria
1. Patients aged less than 18 years
2. Patients with traumatic brain injury requiring treatment of intracranial hypertension
3. Those with relative contraindications to the use of the esophageal Doppler probe, such as orofacial and esophageal injury or other known oropharyngeal and esophageal disease

Date of first enrolment
01/03/2003

Date of final enrolment
25/10/2005

Locations

Countries of recruitment
Czech Republic

Study participating centre
Anesthesiology and Intensive Care Department
Plzen
Czech Republic
30460

Sponsor information

Organisation
Charles University (Czech Republic)

Sponsor details
Faculty of Medicine in Plzen
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Sponsor type
University/education

ROR
https://ror.org/024d6js02

Funder(s)

Funder type
Government

Funder Name
The study was supported by the Czech Ministry of Education (project MSM0021620819) and by the Czech Ministry of Health (research grant IGA ND/7712-3).

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	01/08/2007		Yes	No