

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

☐ Prospectively registered

☐ Protocol

Registration date
19/10/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
26/04/2007

Condition category
Injury, Occupational Diseases, Poisoning

☐ 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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)

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**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