

Intraoperative fluid optimisation using stroke volume variation in high risk surgical patients

Submission date 19/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/04/2021	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

Study information

Scientific Title
Intraoperative fluid optimisation using stroke volume variation in high risk surgical patients: a randomised prospective single-centre study

Acronym
SVVOPT

Study objectives

Stroke volume variation guided fluid optimisation during major abdominal surgery in comparison with standard haemodynamic management may reduce organ dysfunction development and postoperative morbidity in high risk surgical patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Research Ethics Committee of University Hospital in Plzen, approved on 14/06/2007

Study design

Open randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Fluid optimisation of high risk surgical patients undergoing major abdominal surgery

Interventions

Patients were randomised into protocol or control group using sealed envelopes method.

Fluid management in control group patients was managed using routine cardiovascular and clinical monitoring.

Haemodynamic optimisation of protocol group patients was provided with colloid boluses of 3 ml/kg guided by stroke volume variation and other haemodynamic variables according to the protocol based on data obtained by Vigileo™/FloTrac™ monitor.

After operation fluid management and overall postoperative care was the same in both groups.

Patients were followed at least 30 days after operation, if hospitalised at this day then till hospital discharge.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Postoperative morbidity based on occurrence (rate and number) of postoperative infectious and organ complications until 30 days after operation.

Key secondary outcome(s)

1. Duration of hospital and intensive care unit (ICU) stay
2. All cause mortality
3. Biochemical parameters of oxygen debt during operation and in early postoperative period (8 hours)

Completion date

30/05/2009

Eligibility

Key inclusion criteria

High risk surgical patients of both gender scheduled for intraabdominal surgery with presumed blood loss of more than 1,000 ml or longer than 120 minutes with open peritoneal cavity.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

120

Key exclusion criteria

1. Patients aged less than 18 years
2. Patients with irregular heart rhythm
3. Those with body weight less than 55 kg or more than 140 kg

Date of first enrolment

01/07/2007

Date of final enrolment

30/05/2009

Locations

Countries of recruitment

Czech Republic

Study participating centre

Department of Anesthesia and Intensive Care
Plzen
Czech Republic
30460

Sponsor information

Organisation

Charles University Teaching Hospital Plzen (Czech Republic)

ROR

<https://ror.org/024d6js02>

Funder(s)

Funder type

Government

Funder Name

Ministry of Education (Czech Republic) (project ref: MSM0021620819)

Alternative Name(s)

Ministry of Education of the Republic of Korea, , MOE

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Korea, South

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		01/01/2010	12/04/2021	Yes	No
Abstract results		13/03/2009		No	No
Other publications	economic evaluation results	22/05/2014		Yes	No