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

Submission date 19/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/10/2009	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 12/04/2021	**Condition category** Surgery	[_] 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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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)

Overall study start date
01/07/2007

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

Age group
Adult

Sex
Both

Target number of participants
120

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)

Sponsor details
Department of Anesthesia and Intensive Care
Alej Svobody 80
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+420 377104381
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Sponsor type
Hospital/treatment centre

Website
http://www.fnplzen.cz/

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

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