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

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|---|---|---|
| **Submission date**<br>19/10/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>29/10/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>12/04/2021 | **Condition category**<br>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**
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

## 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 |

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|---|---|---|---|---|
| Abstract results | economic evaluation results | 13/03/2009 | No | No |
| Other publications | | 22/05/2014 | Yes | No |