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

Submission date 19/10/2009	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 29/10/2009	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
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

**Contact name** Prof Eduard Kasal

## Contact details

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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

Patients aged less than 18 years
 Patients with irregular heart rhythm
 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 Plzen Czech Republic 304 60 +420 377104381 benesj@fnplzen.cz

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