# MINIMAL INVASIVE MONITORING OF VOLUME STATUS IN PATIENTS AFTER MAJOR ABDOMINAL SURGERY.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Gastrointestinal therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39163

**Source**
ToetsingOnline

**Brief title**
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### Condition

- Gastrointestinal therapeutic procedures

**Synonym**
After major abdominal surgery

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Accuracy and precision, Hemodynamic monitoring, Minimal invasive, Propofol

## Outcome measures

### Primary outcome

Cardiac ouput measured with different pulse contour methods to measure CO

compared to thermodilution CO measured with a PAC

### Secondary outcome

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# Study description

### Background summary

Determining volume status is important in critically-ill patients. Currently no gold-standard is available to accurately assess a patient*s volume status and physicians use clinical signs and hemodynamic parameters (like cardiac output) to estimate volume status.
Currently, the Pulmonary Artery Catheter (PAC) is one of the standards to monitor major abdominal surgery patients. Its use, however, is related to complications upsetting its value in other subpopulations like septic patients.
The primary aim of this study is to evaluate the use of less invasive techniques to determine cardiac output (with pulse contour) compared to thermodilution cardiac output measurement with a pulmonary artery catheter. If proven accurate less invasive techniques could replace the PAC in the perioperative monitoring of major abdominal surgery patients.

### Study objective

The primary objectives of this study consist of:
1. To assess the accuracy of different pulse contour methods to measure CO compared to thermodilution CO measured with a PAC in major abdominal surgery patients.
2. To assess the effect of propofol sedation and different hemodynamic challenges (PEEP increase, fluid challenge and passive leg raising) on the accuracy of the measurement of stroke volume variation (SVV), pulse pressure variation (PPV) and CO with different techniques.
3. To assess the accuracy of a novel method to estimate mean systemic filling

pressure against two validated methods.

Secondary objectives consist of:
1. To study the effect of propofol sedation on mean systemic filling pressure.
2. To study the effect of propofol on systemic, venous and arterial resistance.
3. To assess the value of dMAP, dCO, dCVP due to 30° PLR, 5 and 10 cm H2O PEEP, 50 and 100 cc volume challenges to predict fluid loading responsiveness.
4. To assess the value of baseline CO, SVV, SPV, PPV and Pmsf to predict fluid loading responsiveness.

## Study design

Prospective intervention and measurement study

## Intervention

Hemodynamic measurements are performed during propofol infusion at a blood concentration of 4, 2 and 1 µg•mL-1. Subsequently measurements are repeated prior to, 30 seconds after start and 2 minutes after returning to baseline conditions for 30° passive leg raising, PEEP +5 cmH2O and PEEP +10cmH2O. Finally, 500 mL of Voluven is administered in 50 mL bolus with intermediate measurements.

## Study burden and risks

Propofol
Propofol is a GABAA agonist that is widely used as intravenous hypnotic for surgical anesthesia and for sedation during loco-regional anesthesia and at the ICU and PACU. We have experience with propofol in the PACU at the dose range studied and expect minimal hemodynamic side effects in the patients studied. These hemodynamic depressant effects of propofol are the result of peripheral vasodilatation and direct myocardial depression.

Pulmonary Artery Catheter
The standard of perioperative anesthetic care for patients scheduled for major abdominal surgery in the LUMC includes central venous catherisation with or without pulmonary artery catherisation. The insertion of a pulmonary artery catheter is left to the judgment of the attending anesthesiologist. The acquisition of venous access for both the central venous catheter and the PAC is associated with similar complications (id est arterial puncture, bleeding at the injection site, pneumothorax, air- or thrombo-embolism, arrhythmias, infections. Catheterization with a PAC may lead to more specific complications like mild tricuspid insufficiency, pulmonary artery rupture and pulmonary infarction. In a general ICU population the beneficial effects of the monitoring characteristics of the PAC is upset by its complications.. Several subpopulations, however, have shown to have improved survival due to the

monitoring capabilities of the PAC, for example high-risk cardiac surgery. Patients undergoing major abdominal surgery also have an indication for pulmonary artery catheterization for its use is associated with an improved outcome in patients after planned major surgery like those included in our study.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

- Scheduled for ventilation and sedation at the PACU after elective major abdominal surgery (i.e. any type of abdominal surgery with an indication for invasive monitoring with arterial en central venous catheters)
- Aged 18-65 years.
- Being able to give written informed consent prior to surgery.

## Exclusion criteria

- Pregnancy
- Documented or suspected soybean protein and/or relevant drug allergy.
- Morbid obesity (BMI > 35)
- venous pressure (CVP) >18 mm Hg and/ or a cardiac index < 2.0 L•min-1 or dependence on high dosages of inotropic drugs after admittance to the PACU
- Severe arrhythmias
- Renal insufficiency requiring dialysis
- Intra-cardiac shunts
- Symptomatic peripheral vascular disease
- Symptomatic pulmonary disease
- Clinically significant aortic aneurysm
- Significant valvular regurgitation
- Prior diagnosis of aberrant cardiovascular anatomy

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 28-02-2011 |
| Enrollment: | 30 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Propofol |
| Generic name: | Propofol |
| Registration: | Yes - NL intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 01-04-2010 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 24-08-2010 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 13-10-2011 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 31-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| EudraCT | EUCTR2010-019073-15-NL |
| CCMO | NL31886.058.10 |