# THE EFFECT OF THORACIC EPIDURAL ANAESTHESIA WITH GENERAL ANAESTHESIA ON MEAN SYSTEMIC FILLING PRESSURE, VENOUS RETURN AND CARDIAC FUNCTION

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To evaluate the effects of thoracic epidural anaesthesia (TEA) with general anaesthesia on mean systemic filling pressures, arterial- and venous resistance and cardiac output.To assess the hemodynamic effects of vasopressors and fluid loading under...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON40784

**Source**
ToetsingOnline

**Brief title**
Effect of TEA with GA on Pmsf, VR and cardiac function

### Condition

- Other condition

**Synonym**
epidural puncture, Thoracic epidural anesthesia

**Health condition**

effecten van sympathicusblokkade door epidurale anesthesie met algehele anesthesie

**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:** hemodynamic strategy, hemodynamics, TEA

## Outcome measures

### Primary outcome

The primary objectives of this study consist of:

- To evaluate the effects of thoracic epidural anaesthesia (TEA) under general

anaesthesia on mean systemic filling pressures, arterial- and venous resistance

and cardiac output.

### Secondary outcome

Secondary objectives consist of:

- To assess the hemodynamic effects of vasopressors and fluid loading under TEA

with general anaesthesia conditions

- To assess the value of stroke volume variation and pulse pressure

variation,to predict fluid loading responsiveness with TEA.

# Study description

### Background summary

The analgesic effects of thoracic epidural anaesthesia (TEA) have been studied extensively including by our own group. Less is known, however, about the hemodynamic effects of TEA. Consequently, the hemodynamic management after TEA induction varies wildly. Some anaesthetists will start with fluid loading to

address hypotension and others will start using vasopressor medication first.
In this study, we evaluate the hemodynamic effect of TEA on heart function with a Swan-Ganz catheter, venous and arterial pressure, and venous and arterial resistance. Consequently we try to assess the best haemodynamic strategy to offset these hemodynamic effects either by fluid loading or vasopressor medication.

### Study objective

To evaluate the effects of thoracic epidural anaesthesia (TEA) with general anaesthesia on mean systemic filling pressures, arterial- and venous resistance and cardiac output.
To assess the hemodynamic effects of vasopressors and fluid loading under TEA with general anaesthesia conditions.
To assess the value of stroke volume variation and pulse pressure variation to predict fluid loading responsiveness with TEA.

### Study design

Explorative prospective intervention and measurement study

### Intervention

Noradrenalin infusion is started 30 minutes after induction of TEA. The measurements are performed 15 minutes after noradrenalin infusion is started. Noradrenalin infusion is stopped and baseline measurements are repeated after 15 minutes. 4 ml*kg-1 crystalloids are administered in 10 minutes. Study participation is terminated after the final measurements are taken 10 minutes after fluid administration.

### Study burden and risks

Anaesthesia will be according to normal routine with the exception that a longer central line (Swan Ganz catheter) will be placed. This procedure involves no extra risks when performed by anesthesiologists with SG catheters, which is the case in this study.
There will be no extra risks for the patients, but benefits either. Patients will not be paid for inclusion.

## 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

All adult patients scheduled for lung surgery under thoracic epidural and general anaesthesia

## Exclusion criteria

* Participation in a trial on investigational drugs within 3 months prior to the study
* Hemodynamic instability prior to start of measurements with the systolic blood pressure decreasing more than 30% below the pre-anaesthetic value or a mean arterial pressure (MAP) < 60 mm Hg, central 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 induction of general anaesthesia and before TEA.
* Severe arrhythmias
* Intra-cardiac shunts
* Prior diagnosis of aberrant cardiovascular anatomy
* Symptomatic peripheral vascular disease
* Severe chronic obstructive pulmonary disease (GOLD III or IV, or proven existence of lung bullae)
* Clinically significant aortic aneurysm

* Significant valvular regurgitation
* Use of lithium medication
* Diabetes requiring insulin therapy
* On beta blocker or calcium antagonist medication
* Contra-indications to epidural anaesthesia: - Increased risk of bleeding induced by medication or bleeding disorders
- Local infection at the insertion site
- Anatomic abnormalities of the spine

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 27-11-2014 |
| Enrollment: | 10 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 31-07-2014 |
| Application type: | First submission |
| 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 |
|---|---|
| CCMO | NL48092.058.14 |

# Study results

Date completed: 29-11-2018

Actual enrolment: 5