

Cardiac Effects of Thoracic Epidural Anesthesia in Clinical Conditions in Patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25427

Source

NTR

Brief title

N/A

Health condition

TEA, Cardiac Effects, One-Lung ventilation

Sponsors and support

Primary sponsor: UZ Brussel

Laarbeeklaan 101

1090 Jette

Source(s) of monetary or material Support: UZ Brussel

Laarbeeklaan 101

1090 Jette

Intervention

Outcome measures

Primary outcome

The use of TEA in patients undergoing Thoracic surgery.

Secondary outcome

The use of TEA in patients with cardiac failure.

Study description

Background summary

We aim to evaluate the effects of thoracic epidural analgesia on the heart function in human, both during general anesthesia and mechanical ventilation during major abdominal or thoracic surgery or during one-lung ventilation.

Eighty patients provided an 80% power to detect a two-tailed difference of 10% in echocardiographic parameters before and after TEA with an α error of 5% based on an expected standard deviation of 20%.

Four different groups of patients will be studied. All these studies will be performed after approval by the Ethical Commission of the Universitair Ziekenhuis Brussel and written, informed consent of the patients.

Study I: Haemodynamic effects on normal lung-ventilation.

Study II: The effects on two and one-lung ventilation.

Study III: The effects of position during OLV.

Study IV: The effects of right versus left one-lung ventilation in supine position.

Study objective

We aim to evaluate the effects of thoracic epidural analgesia on the heart function in human, both during general anaesthesia and mechanical ventilation during major abdominal or thoracic surgery or during one-lung ventilation.

Study design

1. After intubation;
2. After loading of the TEA;
3. After each sequence of TLV and OLV.

Intervention

Registration of images and measurements with TEE.

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

1. >18 years;
2. Elective abdominal surgery;
3. Lung surgery with TEA.

Exclusion criteria

1. <18 years;
2. Patients with altered heart, renal or lung function.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion	
Date:	27-09-2012
Application type:	First submission

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
NTR-new	NL3494

Register

NTR-old

Other

ISRCTN

ID

NTR3640

MEC UZ BRussel : 2012/143

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A