Thoracic epidural anesthesia with ropivacaine: effects of age on neural blockade and cardiovascular parameters

Published: 06-07-2009
Last updated: 05-05-2024

effects of age on neural blockade and cardiovascular parameters after thoracic epidural anesthesia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33234

Source
ToetsingOnline

Brief title
Age effects in thoracic epidural anesthesia

Condition

- Other condition

Synonym
lung cancer, pneumothorax

Health condition

lokaal anestheticum gebruikt voor epidurale anesthesie

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: onderzoek wordt niet gefinancieerd

Intervention

Keyword: age, cardivascular parameters, ropivacaine, thoracic epidural

Outcome measures

Primary outcome

Neural blockade:

Time to initial onset of analgesia at the T3-T4 dermatomes

Time to initial onset of motor blockade

Time until maximum cephalad spread of analgesia

Time until maximum caudad spread of analgesia

Highest level of analgesia

Maximum numbers of segments blocked

Maximum score of motor block (Bromage scale and ESSAM score)

Cardiovascular:

Left ventricle systolic function

Left ventricle diastolic function

right ventricle systolic function

Secondary outcome

not applicable

Study description

Background summary

The fraction of the population aged 65 years and older is growing very fast. Persons aged 65 years and older now constitute 14 % of the total Dutch population and it is expected that this same group will constitute 23 % of the Dutch population in 2040 (CBS: online).
Lung cancer becomes mostly manifest in the geriatric population [1] and surgical resection is one of the standard therapies. It is to be expected that there will be an increase in the incidence of elderly people presenting with resectable malignancy. Thoracic epidural anesthesia (TEA) combined with general anesthesia (GA) is common practice for this kind of surgery.
To our knowledge there is no study that has tested the influence of age on the extension of neural blockade after thoracic epidural injection of ropivacaine.
It's not known if thoracic epidural anesthesia is influenced by the physiological changes associated with increasing age.

Study objective

effects of age on neural blockade and cardiovascular parameters after thoracic epidural anesthesia

Study design

Prospective observational single center study

Study burden and risks

not applicable

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2

2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

male and female patients
ASA I-III
patients undergoing thoracic surgery under thoracic epidural anesthesia

Exclusion criteria

Diabetes mellitus
Infection of the skin in the area of the epidural site
A history of neurological diseases
A history of bleeding diathesis
Muscle diseases
Hypersensitive to local anesthetics
Pregnancy or lactation
Participation in a trial on investigational drugs within 3 months prior to the study

Study design

Design

Study phase: 4

Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2009
Enrollment:	75
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	naropin
Generic name:	ropivacain
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-07-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-04-2010
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
EudraCT	EUCTR2009-010594-20-NL
CCMO	NL27041.058.09