ISRCTN55650235 https://doi.org/10.1186/ISRCTN55650235

Thoracic epidural or paravertebral analgesia after thoracic surgery

Submission date
11/04/2013

Recruitment status
No longer recruiting

Registration date
21/06/2013

Overall study status
Completed

Last Edited
21/06/2013

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study on patients undergoing thoracic surgery. Inadequate pain treatment after surgery may lead to worsening of lung function because patients may find it difficult to take deep breaths. Standard procedures to reduce pain include thoracic epidural analgesia (TEA) and thoracic paravertebral analgesia (PVB). In principal, TEA can be expected to influence both sides of the thorax, whereas PVB is expected to block only the site of the operation. Our goal is to find out, whether this difference may affect the ability to breathe.

Who can participate?
Patients undergoing thoracic surgery.

What does the study involve?
Patients will be randomly allocated to two groups. One will receive the TEA and the other group PVB. Both procedures are standard pain treatment procedures in our institution. In addition, specialized pain nurses will take care of the appropriate treatment.
The lung function will be assessed by spirometry. The patient is asked to take a deep breath and then exhale into the sensor for as long as possible. The pain levels at rest and during coughing will also be assessed at regular intervals.

What are the possible benefits and risks of participating?
All participants will receive an additional teaching session regarding the pain measures and spirometry. Information obtained from this study may benefit future patient treatment.
By taking part in this study there are no extra risks of physical injury or harm.

Where is the study run from?
Saarland University Medical Center and Saarland University Faculty of Medicine, Homburg, Germany

When is the study starting and how long is it expected to run for?
The study runs from May 2010 to September 2013.

Who is funding the study?
Saarland University Faculty of Medicine, Homburg, Germany

Who is the main contact?
Prof. Dr. Thomas Volk
Thomas.volk@uks.eu

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Volk

Contact details
Saarland University Medical Center
and Saarland University Faculty of Medicine
Homburg
Germany
66421

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40/10

Study information

Scientific Title
Thoracic Epidural or ParaVerteBral Analgesia after thoracic surgery: a randomised controlled trial

Acronym
TEA vs PVB

Study objectives
Lung function after surgery, as measured by forced expiratory volume in 1 second (FeV1) and peak expiratory flow (PEF) is better when a continuous paravertebral catheter is used compared to a continuous thoracic epidural catheter.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethic committee of Auml;rztekammer Saarland, Nr.: 40/10, approved: April 2010

Study design
Randomised unicentric trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Thoracic surgery

Interventions
Continuous thoracic epidural catheter or continuous paravertebral catheter for pain treatment

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
FV1 measured in L/sec and PEF measured in L/sec- lung function parameters from spirometry (FeV1=expiratory flow after 1 second, PEF=peak expiratory flow, FVC=forced vital capacity).

The outcome parameters will be measured before the TEA or PVB placement, 15 minutes afterwards and twice daily until day 3 after surgery.

Secondary outcome measures
1. Pain levels at rest and with coughing (using the verbal numeric rating scale at rest and during coughing)
2. Aggregated incidence of nausea, vomiting, pneumonia, atelectases
3. Mobilisation (time to stand up, to walk)

The outcome parameters will be measured before the TEA or PVB placement, 15 minutes afterwards and twice daily until day 3 after surgery.

Overall study start date
01/01/2012

Completion date
30/07/2013

Eligibility

Key inclusion criteria
1. Aged 18 years old and above
2. American Society of Anesthesiologists (ASA) grade I-III
3. Planned thoracic surgery
4. Accepted procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Relevant liver or renal disease (Kreatinin > 2 mg/dl, Bilirubin > 2 mg/dl)
2. Inability to communicate
3. Relevant cardiac or neurological disease
4. Chronic treatment with opioids or psychiatric drugs
5. Dependencies
6. Body Mass Index > 30
7. ASA > III
8. Contraindication for a neuraxial procedure

Date of first enrolment
01/01/2012

Date of final enrolment
30/07/2013

Locations

Countries of recruitment
Germany

Study participating centre
Saarland University Medical Center
Homburg
Germany
66421

Sponsor information

Organisation
Saarland University Medical Center and Saarland University Faculty of Medicine (Germany)

Sponsor details
c/o Prof. Dr. T. Volk
Homburg
Germany
66421

Sponsor type
Hospital/treatment centre

Website
http://www.uniklinikum-saarland.de/

ROR
https://ror.org/01jdpyv68

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Saarland University Medical Center and Saarland University Faculty of Medicine (Germany)

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