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Paravertebral block versus thoracic epidural analgesia for video-assisted thoracic surgery

Submission date
09/01/2020

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
06/06/2024

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A thoracotomy is a surgery to open the chest. Post-thoracotomy pain can lead to a high incidence of postoperative complications, such as pneumonia and atelectasis, if not adequately controlled. Video-assisted thoracic surgery (VATS) is considered to be less painful and safer and requires a shorter hospital stay than thoracotomy. However, pain remains an issue associated with VATS, especially for the first three days after surgery.
There are numerous pain management options for VATS, including non-steroidal anti-inflammatory drugs (NSAIDs), epidural analgesia, systemic opioids, paravertebral block (PVB), patient-controlled analgesia (PCA), and surgical wound infiltration. The researchers have demonstrated that PVB, which results in lower cumulative dezocine doses and produces fewer side effects than PCA, can provide effective pain relief for patients undergoing VATS. However, TEA has been regarded as the gold standard for managing acute pain after thoracic surgery. The aim of this study is to test whether PVB has similar pain control when compared with TEA.

Who can participate?
Patients aged 18-80, without chronic pain (with no pain medications routinely used), could provide consent to participate and precisely complete a pain assessment, and have resectable solitary pulmonary nodules.

What does the study involve?
Participants are randomly allocated into one of two groups. Participants in the first group undergo single intercostal VATS and afterwards receive patient-controlled PVB for pain relief. Participants in the second group receive thoracic epidural analgesia for pain relief and then undergo single intercostal VATS. All participants' pain levels are assessed, and the number of patients who require extra medication on the three days after the operation is recorded.

What are the possible benefits and risks of participating?
Effective analgesia and fewer side effects are possible benefits. Postoperative analgesic failure is a possible risk.

Where is the study run from?
Second Affiliated Hospital of Zhejiang University (China)

When is the study starting and how long is it expected to run for?
January 2020 to January 2021

Who is funding the study?
Second Affiliated Hospital of Zhejiang University (China)

Who is the main contact?
Prof. Ming Wu
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-451

Study information

Scientific Title
A randomized clinical trial to assess the efficacy of patient-controlled paravertebral block versus thoracic epidural analgesia for patients undergoing single intercostal video-assisted thoracic surgery

Study objectives
It has been demonstrated that paravertebral block, which resulted in lower cumulative dezocine doses and produced fewer side effects than intravenous patient-controlled analgesia, can

provide effective pain relief for patients undergoing video-assisted thoracic surgery. However, epidural analgesia has been regarded as the gold standard for managing acute pain after thoracic surgery. This randomized study was designed to test whether paravertebral block has similar pain control when compared with epidural analgesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/12/2019, Ethics Committee of the Second Affiliated Hospital of Zhejiang University (No. 88 Jiefang Road, Hangzhou city, Zhejiang province, China, 310009; Tel: +86 (0)571 87783759; Email: HREC2013@126.com), ref: 2019-451

Study design
Single-center randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pain in the postoperative period

Interventions
Patients were randomly allocated by a computer-generated random number list to receive patient-controlled PVB (PVB group) or thoracic epidural analgesia (TEA group) for postoperative analgesia before being transferred to the operating room.
1. In the PVB group, patients receive single intercostal video-assisted thoracic surgery and patient-controlled paravertebral block for postoperative analgesia.
2. In the TEA group, patients receive thoracic epidural analgesia for postoperative analgesia and single intercostal video-assisted thoracic surgery
In the case of analgesic failure, intramuscular dezocine 10 mg (Jiangsu, China) was used as rescue medication. The chest tube was removed when there was no air leakage and the volume of drainage was less than 100 mL/24 hours. The criteria for hospital discharge included chest tube removal, adequate oral intake, pain controlled by oral analgesics and assessment of patients' well-being by their attending doctors.

Intervention Type
Procedure/Surgery

Primary outcome measure

Pain measured using the visual analogue score (VAS) in the state of rest and coughing postoperatively at 1, 6, 24, 48, and 72 hours

Secondary outcome measures
1. The number of patients who required rescue medication and the cumulative dezocine dose administered during postoperative days (PODs) 0-3, recorded at 8:00 on PODs 1-4
2. Quality of life measured using the European Organization for Research and Treatment of Cancer (EORCT) general quality of life questionnaire (QLQ-C30) within 1 days prior to surgery, 3 days after the operation
3. Overall satisfaction with analgesic modality measured using a 5-point scale (1=dissatisfied, 5=satisfied) on POD 3
4. Complications after surgery, such as nausea and vomiting, hypertension, chylothorax and atrial fibrillation, recorded after surgery and before discharge

Overall study start date
31/01/2020

Completion date
31/07/2022

Eligibility

Key inclusion criteria
Patients diagnosed with solitary pulmonary nodules and without chronic pain (with no pain medications routinely used) deemed suitable to undergo three-port single-intercostal VATS by surgeons

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
About 85 patients in each group

Total final enrolment
176

Key exclusion criteria
Patients with other malignancies

Date of first enrolment
01/02/2020

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
China

Study participating centre
Second Affiliated Hospital, Zhejiang University School of Medicine
China
31009

Sponsor information

Organisation
Second Affiliated Hospital of Zhejiang University

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Sponsor type
Hospital/treatment centre

Website
http://en.z2hospital.com/

ROR
https://ror.org/059cjpv64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Second Affiliated Hospital of Zhejiang University (China)

Results and Publications

Publication and dissemination plan
Additional documents (such as study protocol, statistical analysis plan etc) will not available in web format, please use the contact details to contact Ming Wu. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Ming Wu (iwuming22@zju.edu.cn).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/08/2023	06/06/2024	Yes	No