

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

<b>Submission date</b> 09/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/06/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> 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  
iwuming22@zju.edu.cn

## Contact information

### Type(s)

Public

### Contact name

Prof Ming Wu

### Contact details

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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 (EORTC) 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

## Sponsor details

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## Sponsor type

Hospital/treatment centre

## Website

<http://en.z2hospital.com/>

## ROR

<https://ror.org/059cjp64>

# 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?
<a href="#">Results article</a>		12/08/2023	06/06/2024	Yes	No