

# Efficacy of patient-controlled paravertebral block for single intercostal video assisted thoracic surgery

<b>Submission date</b> 24/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2018	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Video-assisted thoracic surgery is a type of surgery where a camera is used to view the inside of the chest cavity after making only very small incisions. It is considered to be less painful, safer and requires a shorter hospital stay compared with thoracotomy (surgical opening of the chest). However, pain remains an issue after surgery, especially for the first three days after surgery. Paravertebral block, where local anaesthetic is injected through a catheter (tube) to 'block' the spinal nerve, has been proven to control pain after thoracotomy. The aim of this study is to find out whether patient-controlled paravertebral block can provide pain relief for patients compared with the usual pain management.

### Who can participate?

Patients aged 18 to 80 who require video-assisted thoracic surgery

### What does the study involve?

Participants are randomly allocated into one of two groups. Participants in the first group undergo surgery and afterwards receive patient-controlled paravertebral block for pain relief. Participants in the second group undergo surgery and afterwards receive patient-controlled pain relief intravenously (injected into a vein). 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?

Participants may benefit from pain relief and fewer side effects. The possible risk is that the treatment may fail to relieve pain.

### 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?

June 2015 to January 2017

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

Who is the main contact?  
Prof. Ming Wu

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Ming Wu

**Contact details**  
Department of Thoracic Surgery  
The Second Affiliated Hospital of Zhejiang University  
Hangzhou  
China  
31000

## Additional identifiers

**Protocol serial number**  
N/A

## Study information

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

**Study objectives**  
Paravertebral block has been proven to be effective for pain control after thoracotomy and the traditional approach in performing paravertebral block is by inserting a needle 2.5 to 4 cm lateral to the spinous process of the thoracic vertebra and using the loss of resistance as the superior costotransverse ligament is traversed. In this study, a catheter was placed in the paravertebral space under thoracoscopic guidance by the surgeon for patients undergoing single intercostal video assisted thoracic surgery and this randomized study was designed to testify this technique can also provide effective analgesia for patients comparing with our usual single intercostal video assisted thoracic surgery pain management.

Hypothesis: Patients controlled paravertebral block after single intercostal video assisted thoracic surgery can provide effective analgesia and fewer side effects than intravenous patients controlled analgesia.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Ethics Committee of the Second Affiliated Hospital of Zhejiang University, 08/05/2015

**Study design**

Single-center randomized study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Pain in the postoperative period

**Interventions**

Patients are randomised into two groups:

1. In the PVB group, patients receive single intercostal video-assisted thoracic surgery and patient-controlled paravertebral block for postoperative analgesia.
2. In the PCA group, patients receive single intercostal video-assisted thoracic surgery and intravenous patient-controlled analgesia for postoperative analgesia.

Intramuscular dezocine is used as a rescue medication for both groups. The chest tube is removed when there is no air leakage during coughing and the volume of drainage is less than 100ml/24h. Patients are discharged after removal.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Pain after surgery, measured using visual analogue score (VAS) until day 3 after surgery

**Key secondary outcome(s)**

1. The number of patients who receive rescue medication, measured on postoperative days 0, 1, 2 and 3
2. Complications after surgery, such as nausea and vomiting, hypertension, chylothorax and atrial fibrillation, measured after surgery and before discharge
3. The number of patients who are capable of a good cough, measured on postoperative days 0, 1, 2 and 3
4. Total hospital stay, measured on discharge
5. Time in the ICU, measured on discharge
6. Mortality within 30 days

**Completion date**

31/01/2017

**Eligibility****Key inclusion criteria**

1. Patients diagnosed with solitary pulmonary nodule and spontaneous pneumothorax
2. Suitable for single intercostal video assisted thoracic surgery
3. Aged 18 to 80

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients with unresectable tumors
2. Older than 80 years old

**Date of first enrolment**

01/06/2015

**Date of final enrolment**

31/12/2016

**Locations****Countries of recruitment**

China

**Study participating centre**

Second Affiliated Hospital of Zhejiang University

No. 88 Jiefang Road

Hangzhou

China

310000

**Sponsor information****Organisation**

Second Affiliated Hospital of Zhejiang University

ROR

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

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Second Affiliated Hospital of Zhejiang University (China)

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Zixiang Wu (zixiang0717@126.com)

**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>	results	01/09/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes