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

Submission date
24/10/2016

Recruitment status
No longer recruiting

Registration date
18/11/2016

Overall study status
Completed

Last Edited
11/07/2018

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures

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

Overall study start date
01/06/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130 patients in each group

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

Sponsor details
No. 88 Jiefang Road
Hangzhou
China
31000

Sponsor type
Hospital/treatment centre

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
To be confirmed at a later date

Intention to publish date
31/01/2018

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?
Results article	results	01/09/2018		Yes	No