

# Study to identify the best anesthetic therapy for the control of postoperative pain after videothoracoscopic thoracic surgery

<b>Submission date</b> 29/12/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/04/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A lung resection is a type of surgical procedure where part of the lung (or lungs) is removed. This is a common procedure in patients suffering from lung cancer, as it allows for the cancerous tissue to be removed, preventing the cancer from spreading. In some cases, this is done using a technique called a video thoracoscopy, in which a small camera on the end of a flexible tube is inserted into the surgical wound so that the surgeon can accurately see what they are doing during the procedure. This helps to improve accuracy only the necessary amount of tissue is removed. When patients are having this procedure, they usually also have an injection of a steroid or other medication around the intercostal nerves that are found under each rib (thoracic intercostal block) to provide pain relief. The intradural morphine block, also known as spinal anaesthesia, is another kind of pain relieving injection which is much less commonly used in lung surgery patients. It involves receiving an injection of morphine into the spine to provide pain relief. The aim of this study is to compare the effectiveness of these two techniques in providing pain relief during and after lung resection via video thoracoscopy.

### Who can participate?

Adults who are undergoing lung resection via video thoracoscopy.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive an intercostal block with a drug called levobupivacaine (a numbing medicine) before their surgery. Those in the second group receive intradural morphine (a pain-relieving drug) into the spine before their surgery. All participants undergo their lung resection surgery as per standard practice and are monitored for side effects during and after their surgery. Participants in both groups are asked to rate their pain levels at the start of the study, 6, 12, 24 and 48 hours later, and then 6 and 12 months later.

### What are the possible benefits and risks of participating?

There are no direct benefits involved with participating. Since both techniques are routinely used, participants will not be at greater risk than usual clinical practice.

Where is the study run from?  
Donostia University Hospital (Spain)

When is the study starting and how long is it expected to run for?  
December 2015 to February 2019

Who is funding the study?  
Donostia University Hospital (Spain)

Who is the main contact?  
Dr Silvia González Santos, dra\_sgsantos@yahoo.es

## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
ID1

## Study information

**Scientific Title**  
Analgesic Efficacy of Intradural Morphine Versus Intercostal Block in the postoperative period of major pulmonary resection by videothoracoscopy

**Acronym**  
AEIMVIB

**Study objectives**  
Intradural morphine is more effective in pain control than intercostal block in the postoperative period of major resection by videothoracoscopy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Single-centre randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Pain control after videothoracoscopic major resection

**Interventions**

Current intervention as of 15/02/2022:

Participants are randomised to one of two groups using opaque envelopes.

Control group: Participants receive an intercostal block with Levobupivacaine 0.5%, with infiltration at the level of the upper incision and two upper and lower spaces

Intervention group: Participants receive intradural morphine at the L2-L3 or L3-L4 level, with the administration of morphic chloride (150 mcg if the patient measures <1.60 m and <60 kg, 200 mcg if height between 1.60 and 1.80 m and weight between 60 and 100 kg and 250 mcg, if height >1.80 m and weight >100 kg)

Participants in both groups are followed up for a total of 12 months.

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Previous intervention as of 03/02/2022:

Participants are randomised to one of two groups using opaque envelopes.

Control group: Participants receive an intercostal block with Levobupivacaine 0.5%, with infiltration at the level of the upper incision and two upper and lower spaces

Intervention group: Participants receive intradural morphine at the L2-L3 or L3-L4 level, with the administration of morphic chloride (150 mcg if the patient measures <1.50 m and <60 kg, 200 mcg if height between 1.50 and 1.80 m and weight between 60 and 100 kg and 250 mcg, if height >1.80 m and weight >100 kg)

Participants in both groups are followed up for a total of 12 months.

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Previous intervention:

Participants are randomised to one of two groups using opaque envelopes.

Control group: Participants receive an intercostal block with 0.75% Ropivacaine (maximum dose 225mg) with infiltration at the level of the upper incision and two upper and lower spaces

Intervention group: Participants receive intradural morphine at the L2-L3 or L3-L4 level, with the administration of morphic chloride (150 mcg if the patient measures <1.50 m and <60 kg, 200 mcg if height between 1.50 and 1.80 m and weight between 60 and 100 kg and 250 mcg, if height > 1.80 and weight > 100 kg)

Participants in both groups are followed up for a total of 12 months.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Morphine, levobupivacaine

### **Primary outcome(s)**

Pain at rest and with cough (0 h, 6 h, 12 h, 24 h, 48 h, 6 months and 12 months)

### **Key secondary outcome(s)**

1. Sedation is measured using the Richmond agitation sedation scale 24 hours after surgery
2. Nausea or vomiting is measured by patient interview and medical and nursery record review 24 and 48 hours after surgery
3. Pruritus is measured by patient interview and medical and nursery record review 24 and 48 hours after surgery
4. General satisfaction of pain management is measured by patient interview at the time of discharge
5. Respiratory complications (atelectasis requiring BCF, pneumonia requiring antibiotic, respiratory insufficiency requiring TBI) are measured by patient interview and medical record review during postoperative days
6. Cardiac complications (ACxFA, AMI, ICC) are measured by by patient interview and medical record review during postoperative days
7. Urinary retention with resondation or impossibility of urinary catheter extraction is assessed by patient interview and medical record review during postoperative days
8. Days to ambulation is measured by patient interview and medical and nursery record review during postoperative days
9. Mortality is measured using medical record review at 90 days

### **Completion date**

28/02/2019

## **Eligibility**

### **Key inclusion criteria**

1. Undergoing to lung resection (lobectomies, bilobectomies, or segmentectomies) by videothoracoscopy
2. Age 18 years and over

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

181

**Key exclusion criteria**

1. Age <18 years
2. History of drug abuse
3. Patients with chronic pain treated with opioids
4. Any contraindication for the accomplishment of intradural or intercostal block (hemorrhagic diseases, recent systemic or local infections, allergy to local anesthetics or morphine, CNS expansive processes, hydrocephalus or alterations of the lumbar spine that contraindicate the lumbar puncture)
5. Patients who do not want to participate or mentally not competent
6. Surgeries converted to thoracotomy

**Date of first enrolment**

01/12/2017

**Date of final enrolment**

15/04/2020

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

Spain

**Study participating centre**

**Donostia University Hospital**

Paseo Beguiristain s/n.

Donostia

Spain

20014

**Sponsor information**

## Organisation

Donostia University Hospital

## ROR

<https://ror.org/04fkwzm96>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Donostia University Hospital

## Results and Publications

### Individual participant data (IPD) sharing plan

Not provided at registration

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		28/03/2024	15/04/2024	Yes	No
<a href="#">Basic results</a>		07/04/2021	07/04/2021	No	No
<a href="#">Protocol file</a>	version 4	22/08/2017	01/09/2022	No	No