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

Submission date 29/12/2016	<b>Recruitment status</b> No longer recruiting	<ul><li>[X] Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 30/12/2016	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 15/04/2024	<b>Condition category</b> Surgery	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 intecostal 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** Dr Silvia González Santos

#### Contact details

Anaesthesia and Resuscitation Department Donostia University Hospital Paseo Dr. Beguiristain s/n 20014 Donostia Spain 20014 +34 943007000 (Ext. 3670) dra\_sgsantos@yahoo.es

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

**Secondary study design** Randomised controlled 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 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.

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.

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 measure

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

### Secondary outcome measures

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 days9. Mortality is measured using medical record review at 90 days

Overall study start date 01/12/2015

**Completion date** 

28/02/2019

# Eligibility

#### Key inclusion criteria

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

Participant type(s) Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 120-140

**Total final enrolment** 181

### Key exclusion criteria

1. Åge <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

**Sponsor details** Paseo Beguiristain s/n Donostia Spain 20014

**Sponsor type** Hospital/treatment centre

ROR https://ror.org/04fkwzm96

# Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Donostia University Hospital

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a peer reviewed journal.

#### Intention to publish date

31/12/2022

#### 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?
<u>Basic results</u>		07/04/2021	07/04/2021	No	No
<u>Protocol file</u>	version 4	22/08/2017	01/09/2022	No	No
<u>Results article</u>		28/03/2024	15/04/2024	Yes	No