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

Submission date
29/12/2016

Recruitment status
No longer recruiting

Registration date
30/12/2016

Overall study status
Completed

Last Edited
15/04/2024

Condition category
Surgery

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

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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.

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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 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 days
9. 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
1. Undergoing to lung resection (lobectomies, bilobectomies, or segmentectomies) by videothoracoscopy
2. 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. 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

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