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A study comparing an injection on the fat near the phrenic nerve in the chest cavity reduces the pain after open thoractomy surgery

Submission date
02/02/2016

Recruitment status
No longer recruiting

Registration date
27/07/2016

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Long-term conditions which affect the lungs (chronic lung disease) and the airways are a growing problem worldwide. People with CLD are likely to experience breathlessness and chest pain, especially when exerting themselves, and so sufferers tend to avoid exercise. This can lead to their lung conditions getting worse, causing disability that is both a source of suffering and strain on the health services. Medication can be used to help improve the symptoms of CLD however it does not stop the disease from getting worse in the long term. In many cases, patients undergo surgical procedures such as a lung resection (a procedure in which part of the lung is removed). In order to gain access to the lungs in this procedure, a surgical cut is made in side of the chest (thoracotomy). Following this type of surgery, patients are often in a great deal of pain at the surgical site which can interfere with their recovery. Nerve block procedures are used more and more for post-operative pain relief. An injection of a drug such as bupavacaine (a numbing agent) around a nerve can numb the area, so the patient does not feel pain in the areas the nerve supplies. The aim of this study is to find out whether a nerve block to the phrenic nerve (nerve that supplies the diaphragm, the main muscle involved in breathing) can help to reduce post-operative pain and improve recovery in patients who have had a thoracotomy.

Who can participate?
Adult patients who are having open thoracic (chest) surgery by choice.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive an injection of 10ml 0.25% bupivacaine into the fat surrounding the phrenic nerve (nerve that supplies the diaphragm) at the end of their surgery just before the lungs are re-inflated and the surgical incision is closed. Participants in the second group do not receive any injection into the fat near the phrenic nerve. Participants are asked to rate their level of pain two hours before surgery, and then one, three, six, 12, 24, 48 and 72 hours after surgery. At these times, their lung function is also measured by blowing into a tube attached to a machine which measures how much they are able to blow out.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in this study. There is a small risk of developing complications following the nerve block procedure, such as pain, numbness or dizziness.

Where is the study run from?
Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2014 to September 2015

Who is funding the study?
University Hospital of South Manchester NHS Foundation Trust (UK)

Who is the main contact?
Mr Rajesh Shah

Contact information

Type(s)
Scientific

Contact name
Mr Rajesh Shah

Contact details
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South Manchester
United Kingdom
M23 9LT

Additional identifiers

Protocol serial number
14/NW/0003

Study information

Scientific Title
A randomised prospective study comparing phrenic nerve infiltration vs non-phrenic nerve infiltration on open thoracotomy

Study objectives
The infiltration of phrenic nerve during surgery may reduce the certain focal areas of pain associated with an open thoracotomy surgical procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Greater Manchester North West Ethics Committee, 05/04/2014, ref: 14/NW/003

Study design
Single-centre single-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Open thoractomy patients undergoing single lung lobe resection

Interventions
Participants are randomly allocated to on of two groups.

Intervention group: Participants receive infiltration of 10ml of 0.25% bupavacaine into the periphrenic fat pad above and below hilum level just before the expansion of the lung and closure of the thoractomy. The phernic nerve infiltration will be performed using a 22-G spinal needle (Becton – Dickinson) inserted into the fat pad near the phrenic nerve at the level of the diaphragm. This fat pad is a site for infiltration, which will act as a reservoir for the local anaesthetic and reducing the risk of intraneural injection and nerve damage.

Control group: Participants do not receive any injection in the fat near the phrenic nerve.

Participants in both groups have their lung function assessed 1, 3, 6,12, 24, 48 and 72 hours post-operatively, as well being monitored for respiratory complications.

Intervention Type
Other

Primary outcome(s)
1. Pain is measured using the Likert scale pain scoring system at baseline (2 hours pre-operatively), 1, 3, 6, 12, 24, 48 and 72 hours postoperatively
2. Effect of pain on postoperative peak flow pressure is measured using spirometry at baseline (2 hours pre-operatively), 1, 3, 6, 12, 24, 48 and 72 hours postoperatively

Key secondary outcome(s)
1. Use of pain medications is assessed by reviewing patient drug charts on discharge from hospital
2. Mobilisation is assessed by reviewing physiotherapy records on discharge from hospital

Completion date
20/09/2015

Eligibility

Key inclusion criteria

1. All patients undergoing routine elective thoracic surgery especially open thoracotomy procedure with patient-controlled analgesia (PCA) and epipleural insertion
2. Provision of written informed consent
3. Aged 18 years or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who are having epidural anaesthesia
2. Patients undergoing emergency operation
3. Refusal to take part in the study

Date of first enrolment
30/06/2014

Date of final enrolment
05/05/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
Southmoor Road
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of South Manchester NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

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	22/01/2019	Yes	No