

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Surgery	<input type="checkbox"/> 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 bupivacaine (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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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% bupivacaine into the periphrenic fat pad above and below hilum level just before the expansion of the lung and closure of the thoractomy. The phrenic 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 measure

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

Secondary outcome measures

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

Overall study start date

20/09/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

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

England

United Kingdom

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

Sponsor details

Research and Development

NIHR building

University Hospital of South Manchester NHS Foundation Trust

South Manchester

United Kingdom

M23 9LT

Sponsor type

Research organisation

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

Publication and dissemination plan

Planned dissemination of abstracts in thoracic surgery meetings and results publications in scientific journals.

Intention to publish date

31/12/2016

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