

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

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<b>Registration date</b> 27/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> 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

1st floor, CT theatres  
Wythenshawe Hospital  
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)

## **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 one 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(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?
<a href="#">Results article</a>	results	01/09/2018	22/01/2019	Yes	No