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Thoracic epidural blockade verses paravertebral blockade in reducing chronic post thoracotomy pain

Submission date
15/07/2015

Recruitment status
No longer recruiting

Registration date
15/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Surgery through the side of the chest (thoracotomy), usually to treat lung cancer, causes pain postoperatively, with more than a half of patients developing chronic post-thoracotomy pain (CPTP) which can last months or years. This pain can be severe and debilitating, leading to more frequent GP visits, longer sick leave or even unemployment. CPTP will remain a significant health care and economic burden as there has been an increase in lung operations over the last decade of around 60%, and the trend is likely to continue. Thoracic epidural blockade (TEB), numbing nerves on both sides of the chest, and paravertebral blockade (PVB), targeting pain relief to the side of the surgery are two common techniques that provide good pain relief. But crucially, there is evidence that PVB may reduce the likelihood of chronic pain developing afterwards because of its different sites of action from TEB. Here, we seek to investigate clinical and cost effectiveness of PVB on CPTP in a well-designed randomised trial. However there are certain aspects of the trial that need further clarification - such as how many patients will consent to being randomised to PVB or TEB? Which factors motivate, or become barriers for clinicians and patients to agree to be randomised? Are there any technical difficulties that need to be overcome in order to conduct a full trial? This pilot study aims to answer these questions so that the subsequent randomised controlled trial has the best chance of gaining funding and being successful.

Who can participate?
Adults (aged at least 18) about to have a thoracotomy.

What does the study involve?
Participants are randomly allocated to receive TEB or PVB during surgery. Study data is collected before and after surgery and study questionnaires are also completed before surgery and then again after 24 hours, 48 hours, 72 hours, 3 months and then, finally, 6 months after surgery.

What are the possible benefits and risks of participating?
This study is intended to show whether it is feasible to carry out further research with a larger group of patients and to guide us in how such future research, if funded, should be conducted.

Whilst there may be no immediate benefits to the participants, the information gained from this study will help us to develop a larger study which will investigate the impact of paravertebral blockade and thoracic epidural blockade has on long term pain and pain relief for patients. The overall aim will be to improve the longer term pain relief and future care for patients who have lung surgery. Paravertebral block and thoracic epidural block are both widely used to provide pain relief to patients after major surgery. Although they provide good quality pain relief, the side effects may include discomfort on insertion, low blood pressure, itchy skin, headache, nausea and vomiting. Very rare complications can include infection, temporary or permanent nerve damage. Taking part in the study will not add to these side effects and participants will be closely monitored by the research team.

Where is the study run from?
Birmingham Heartlands Hospital NHS Trust and Wythenshawe Hospital, Manchester (UK)

When is the study starting and how long is it expected to run for?
December 2014 to December 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Amy Kerr

Contact information

Type(s)
Public

Contact name
Mrs Amy Kerr

Contact details
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Additional identifiers

Protocol serial number
18096

Study information

Scientific Title
A randomised controlled trial to investigate the effectiveness of ThOracic epidural and Paravertebral blockade In reducing Chronic post-thoracotomy pain

Acronym
TOPIC

Study objectives
The overall aim of this research is to determine in adult patients who undergo open chest surgery whether perioperative paravertebral blockade (PVB) at thoracotomy results in reducing chronic post-thoracotomy pain compared to thoracic epidural blockade (TEB). To answer this research question with authoritative evidence of clinical and cost effectiveness of PVB, a multi-centre randomised controlled trial with a parallel health economic evaluation is required. However, feasibility studies are the best way to assess feasibility of a large, expensive full-scale study, and in fact are an almost essential pre-requisite. Conducting feasibility prior to the main study can enhance the likelihood of success of the main study and potentially help to avoid doomed main studies. We have therefore designed this multicentre feasibility study comparing the effectiveness of thoracic epidural blockade and paravertebral blockade in reducing chronic post-thoracotomy pain. This study will evaluate feasibility of a substantive trial and study processes by making the following qualitative and quantitative assessments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Derby, 24/12/2014, ref: 14/EM/1280

Study design
Both; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anaesthesia, perioperative medicine and pain management

Interventions
All adults undergoing planned elective thoracotomy at study sites fulfilling inclusion and exclusion criteria will be approached and the trial written information sheets will be given to them and the study will be discussed fully. Written Informed consent will be obtained. Patients who consent to participate in the trial will be randomised to either receiving TEB or PVB arm which will be delivered during the patients surgery by either a surgeon or anaesthetist trained in the study protocol. Patient will be randomised on the morning of the surgery. If either surgeon or anaesthetist is not available to deliver the intervention, randomisation will not go ahead. Pre and post-surgery study data collection will be performed and study questionnaires will be completed pre-surgery baseline 24, 48, 72 hours following surgery, 3 and 6 months after discharge.

Intervention Type
Other

Primary outcome(s)

To establish the number of patients randomised as a proportion of those eligible to enter the study.

Key secondary outcome(s))
1. Assessment of effectiveness of patient identification and screening processes
2. Identification and analysis of any reasons for failure to recruit patients
3. Examination of the educational materials provided to surgeons and anaesthetists to ensure they are fit for purpose
4. Assessment of willingness of surgeons and anaesthetists to participate
5. Assessment of the effectiveness of the randomisation process of patients
6. Assessment of sustainability of single-blinding of patients to treatment allocation
7. Evaluation of robustness of data collection processes during patients hospital stay
8. The proportion of patients followed up at six months
9. Acceptability to and impact on patients of the interventions
10. Assessment of trial processes, including the choice of outcome measures and impact on staff
11. Derivation of the preliminary data from clinical outcome measures to inform the sample size calculation for the substantive study

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Elective open thoracotomy
3. Able to understand the study information and provide written informed consent
4. American Society of Anaesthesiologists physical status I, II or III
5. Not known to be pregnant

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
69

Key exclusion criteria

1. Contraindication to TEB or PVB e.g. known allergy to local anaesthetics
2. Infection near the proposed puncture site
3. Coagulation disorders
4. Thoracic spine disorders
5. Chest wall resection
6. Emergency thoracic surgery
7. Previous thoracotomy
8. Likely inability to comply with completion of the study questionnaires

Date of first enrolment
01/07/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Birmingham Heartlands Hospital NHS Trust (lead)
Critical Care MIDRU
Birmingham Heartlands Hospital
Bordersley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Wythenshawe Hospital
Southmoor Road
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M23 9LT

Sponsor information

Organisation
Heart of England NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2019	22/07/2020	Yes	No
Protocol article		01/12/2016	18/08/2023	Yes	No
HRA research summary			28/06/2023	No	No