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Analgesic efficacy of interpleural and paravertebral block

Submission date 13/10/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/11/2014	**Overall study status** Completed	
Last Edited 02/02/2018	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Injection of local anaesthetic to numb an area of the body is known as regional anaesthesia. This is known to be a very good and safe way of providing pain relief for breast surgery and it avoids many of the side effects of strong pain killers, such as morphine. There are several types of regional anaesthesia used for breast surgery, but at the moment, its not known which one provides the best pain relief. At our institution we commonly use two types of regional anaesthesia - UGTPVB and interpleural block. UGTPVB involves an injection of local anaesthetic to a small area beside the spine which then spreads and blocks the nerves to the chest. In interpleural block, the local anaesthetic is injected into the lining of the lung which then spreads to block the same nerves. Both injections are performed once the patient has been anaesthetised. This study will help anaesthetists and patients decide which of these two pain relief techniques work best. We suspect that UGTPVB provides better pain relief as local anaesthetic is injected close to its point of action but this is not proven. It is easier and quicker to give patients the interpleural block so if we find out that the two techniques provide equal pain relief then interpleural block will be an attractive option for anaesthetists.

Who can participate?
Female patients aged between 18-85 and undergoing a mastectomy at the Royal Victoria Infirmary (UK)

What does the study involve?
Participants are randomly allocated to have either interpleural or UGTPVB. All patients receive the same anaesthetic regardless of technique. Once the patients are anaesthetised, the block is performed by an anaesthetist who is an expert in regional anaesthesia. No one else is aware of which block each patient receives. The patients proceed with their anaesthetic and surgery as normal. After the operation all patients record their pain and nausea scores every six hours and the research team record the amount of morphine each patient needs for the first 24 hours after surgery. We will analyse the data to determine whether USGPVB provides better pain relief than interpleural block. The results will be submitted to an anaesthetic peer reviewed journal for publication.

What are the possible benefits and risks of participating?
By enrolling in the study the participant will receive one of the most effective types of pain relief for their operation. Studies have shown that both techniques provide excellent pain relief with few side effects- especially when compared to morphine based pain relief. Regional anaesthesia is also known to reduce chronic scar pain, a common problem following mastectomy, and there is some evidence that the use of regional anaesthesia may help prevent the cancer from returning. Complications of either type of block are rare and already standard treatments. The most likely complications of a paravertebral block include low blood pressure, bleeding at the site of the injection and puncturing of the lung lining. The most common risk of interpleural block is developing a pneumothorax. Serious complications of both injections are very rare. In any technique where local anaesthetics are used there is a risk of toxicity. The most likely serious complication of local anaesthetic toxicity is a seizure and this occurs in around 1 in 10,000 patients.

Where is the study run from?
The Royal Victoria Infirmary hospital in Newcastle-Upon-Tyne (UK)

When is the study starting and how long is it expected to run for?
January 2015 to January 2016

Who is funding the study?
1. Newcastle-upon-Tyne Hospitals NHS Foundation Trust (UK)
2. National Institute of Academic Anaesthesia (UK) - pending

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3

Study information

Scientific Title
A comparison of the analgesic efficacy of interpleural and ultrasound guided thoracic paravertebral block for mastectomy: a double blinded randomised trial

Acronym
PVIPM

Study objectives
Does ultrasound guided paravertebral block provide better analgesia than interpleural block for patients undergoing simple mastectomy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised double-blind 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
Analgesia for mastectomy

Interventions
1. Group one will receive ultrasound guided paravertebral block and a standardised anaesthetic
2. Group two will receive interpleural block and the same standardised anaesthetic

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
VAS pain score measured at six hourly intervals for the first 24 hours following mastectomy

Secondary outcome measures
1. Nausea and vomiting rate
2. 24-hour morphine consumption

Overall study start date
01/01/2015

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Female patients
2. Between the age of 18 and 85
3. Undergoing elective mastectomy at the RVI

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
70

Key exclusion criteria
1. Any procedure other than sentinel node biopsy in addition to simple mastectomy. This includes axillary node clearance and reconstructions.
2. BMI>35
3. Musculoskeletal deformity
4. Local infection at paravertebral or interpleural injection site
5. Coagulopathy
6. Respiratory disease which limits functional capacity
7. Neurological disease

8. Allergy or contraindication to local anaesthetics, opiates, paracetamol, parecoxib, volatile or intravenous anaesthetics and neuromuscular blockade.
9. Chronic pain treated by long term opiates
10. Psychiatric disease
11. Pregnancy or breast feeding
12. Patient refusal or incapacity
13. Anticipated difficult intubation which would preclude the use of neuromuscular blockade
14. Day case procedure planned

Date of first enrolment
01/01/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle Upon Tyne
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NE1 4LP

Sponsor information

Organisation
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
National Institute of Academic Anaesthesia (UK) - pending

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration