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Advanced pain relief for rib fractures following trauma: a multicentre trial with patients allocated to either treatment or placebo looking at possibility of a larger scale study

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
09/03/2022

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
We don't have a perfect way to give people pain relief for broken ribs, but doctors try combinations of tablets, strong painkillers in a drip, epidural injections and even surgery to help. Physiotherapy and careful nursing care are also really important to help people recover. But there is no perfect pain relief 'recipe' that works for every person every time.
The purpose of this study is to test if a new method of pain relief - called an erector spinae plane (ESP) block - can help people with broken ribs get better pain relief and reduce their risk of getting chest problems as a result of their broken ribs. ESP blocks are injections, like an epidural, that are simple to do and suitable for almost everyone. We know they help people after operations but we don't know if they can help with broken ribs. An ESP block involves injecting local anaesthetic into the back to numb nerves which supply the broken ribs. We want to know if performing an ESP block soon after someone has broken their ribs can improve their health during their hospital admission, specifically the pain they suffer and their risk of needing extra oxygen or developing a chest infection.
To test ESP blocks properly, we need to do a large clinical trial at lots of hospitals that care for people with broken ribs. Before we launch into such a big project, it is important to 'test the water' and make sure we design that trial properly and understand what problems we might encounter. This is called a feasibility study and is what is being proposed here.
This feasibility study will run at three UK hospitals in Nottingham, Manchester, and London, caring for people with broken ribs. We will see if adding an ESP block to the existing 'recipes' for pain relief for broken ribs makes a difference to 50 people's pain relief and risk of becoming more unwell. We will collect data (for example, pain scores) and do interviews (with patients and local researchers), which will help us design a well-thought-out large trial. If this feasibility study works, we will ask for NHS support for a larger trial within 12 months of finishing this project.

Who can participate?
Patients aged 18 years and older who are a new admission to a major trauma centre with rib fracture

What does the study involve?
This study is called a randomised controlled trial because we need to compare different treatments between groups of patients. To try and make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The results are then compared. In this trial, there are two groups: people who receive an ESP block alongside other pain relief, and people who receive a placebo, or “dummy” ESP block alongside other pain relief.

What are the possible benefits and risks of participating?
There is no guarantee that taking part in the research will benefit you; however, you will be helping us understand this injury better and potentially improve care for patients in the future. Common risks of ESP blocks are bleeding, infection or the injection needing to be repeated. A rare complication can be local anaesthetic toxicity. You will be closely monitored for all possible side effects.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
May 2021 to March 2024

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

Who is the main contact?
Harriet Howard, Harriet.Howard2@nuh.nhs.uk

Contact information

Type(s)
Scientific

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Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299011

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51544, NIHR202195, IRAS 299011

Study information

Scientific Title
Erector Spinae Plane blocks for the Early Analgesia of Rib fractures in trauma: a multicentre pilot randomised controlled trial with feasibility and embedded qualitative assessment

Acronym
ESPEAR

Study objectives
To determine feasibility of progression to a definitive RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/02/2022, South Central - Oxford B Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8270; oxfordb.rec@hra.nhs.uk), ref: 22/SC/005

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Erector spinae plane blocks for the early analgesia of rib fractures in trauma

Interventions
Randomisation will be performed to a 1:1 ratio using a web-based automated computer-generated minimisation with treatment groups balanced for: age, gender, polytrauma and unilateral or bilateral rib fractures. Other than the allocated intervention, both groups will be followed up in the same way to exclude bias beyond procedures necessary for the allocation of treatment.

Randomisation will be to two groups:
1. ESP block plus multimodal analgesia (intervention)
2. Sham (or 'dummy') ESP block plus multimodal analgesia (control)

Participants randomised to ESP block plus multimodal analgesia (intervention) will receive an US-guided ESP block. An initial injection of 30ml of 0.25% levo-bupivacaine will be placed, followed by catheter programmed-intermittent boluses of 15ml 0.125% levo-bupivacaine given 3 hourly with option for patient or clinician top up of 5 ml up to every 1 hour. This is in keeping with the product license of levo-bupivacaine.

Participants allocated to the intervention will additionally receive standard supportive care and multimodal analgesia according to British Orthopaedic Association 2016 guidelines. The site-specific adoption of multimodal analgesia regimes will be reviewed as part of the site feasibility.

Sham Group: Participants randomised to Sham ESP block plus multimodal analgesia (control) will receive a sham (also known as a 'dummy') ultrasound-guided ESP block in a sitting or lateral decubitus position determined by optimal patient comfort. The sham block will target the vertebral transverse process corresponding to the mid-point of the consecutively fractured ribs on the side of moderate or severe unilateral pain. A single 1 ml subcutaneous injection will be made and a perineural catheter applied and affixed by skin-glue externally on the skin, which will be dressed and connected to an infusion pump with a patient-button, which will remain turned off. Participants allocated to the comparator will additionally receive standard supportive care and multimodal analgesia according to individual study site protocol as per the intervention arm.

Qualitative research will be embedded within the ESPEAR RCT feasibility study to provide insights into the feasibility and design of a main RCT trial. It will focus on two key aspects:
1. Understanding the acceptability and feasibility of delivering the intervention/control in practice
2. Exploring patients’ experience of trial participation and acceptability of interventions

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Any long acting local anaesthetic

Primary outcome measure
Feasibility primary outcome measures:
1. Recruitment rate – using trial database – measured at the end of the trial recruitment period
2. Retention rate – measured using trial database – measured at the end of the trial follow-up period
3. Barriers and facilitators to recruitment and retention among participants and recruitment site staff (anaesthetists, allied health professionals, surgeons and research staff) with regard to the acceptability of the trial intervention – measured using interviews, qualitative assessment

Feasibility secondary outcome measures measured at the end of the trial follow-up period:
4. Willingness of anaesthetists to randomise patients to intervention or control and willingness of potential participants to randomisation – measured using recruitment logs and interviews
5. Causes of protocol violation and trial withdrawal – measured using trial logs and interviews
6. Completeness of data arising from the trial - measured using database
7. Fidelity of the trial intervention in terms of ESP catheter dislodgement, blockage or other technical failure - measured using CRFs/database
8. Acceptability of the intervention to participants – measured using questionnaires and interviews
9. Complications of the intervention – recorded on AE/SAE log and database

Secondary outcome measures
1. Baseline demographics
2. Static chest wall pain (SF-MPQ-2) at baseline, 24, 48, 72 hours
3. Dynamic chest wall pain (modified functional pain scale) at baseline, 24, 48, 72 hours
4. Spirometry (Forced vital capacity) at baseline, 3, 6, 9, 12, 24, 48, 72 hours
5. Analgesic consumption measured using hospital drug chart at baseline(cumulative dose 24 hours prior to receiving intervention), then again at 24, 48 and 72 hours post-intervention
6. Opioid-related side-effects measured at baseline, 24, 48, 72 hours using:
6.1. Constipation, defined as the absence of bowel movement in the preceding 24-hour period
6.2. Nausea or vomiting, scored on a 5-point scale (0 = no nausea or vomiting; 1 = mild nausea, no treatment required; 2 = nausea, anti-emetic administered; 3 = vomiting, anti-emetics administered; 4 = nausea or vomiting unresponsive to anti-emetic therapy)
6.3. Pruritis scored on an 11-point numerical rating scale
6.4. Opioid-induced sedation, scored on the Modified Observer's Assessment of Alertness /Sedation scale
7. Additional RA procedures at baseline, 24, 48 and 72 hours will be recorded on CRFs
8. Complications of RA measured at 24, 48, 72 hours using:
8.1. Treatment for local anaesthetic toxicity, defined as administration of intralipid therapy in the preceding 24-hour period
8.2. Bleeding or infection at the intervention insertion site
8.3. Catheter dislodgement requiring re-sited intervention in the preceding 24-hour period
9. Oxygen requirement measured as maximum flow rate of supplemental oxygen administered

to participant immediately prior to receipt of trial intervention (defined as trial baseline), then at the following time points following receipt of intervention, 3, 6, 9, 12, 24 hours, 48 hours and 72 hours.
10. Condition-specific outcome measure measured using Outcomes after chest trauma score (OCTS) at baseline, 72 hours, 6 weeks
11. Pneumonia measured using drug chart/CRF defined as administration of antibiotics for community- or hospital-acquired pneumonia assessed in the 24 hours prior to receipt of trial intervention (defined as trial baseline), then at the following time points at baseline, 24, 48, 72 hours, and 6 weeks
12. Escalation to critical care measured using local hospital system at baseline, 24, 48, 72 hours, and 6 weeks
13. Length of hospital stay measured using local hospital system at 6 weeks
14. Quality of life (EQ-5D-5L) at baseline, 24, 48, 72 hours, 6 weeks
15. Mortality measured using local hospital system/GP contact at 6 weeks
16. Review/Reporting of AEs/SAEs – all AEs/SAEs will be logged at the trial coordinating centre (Nottingham) at 12, 24, 48, 72 hours, and 6 weeks

Overall study start date
01/05/2021

Completion date
13/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/10/2023:

1. 18 years and older
2. New admission to major trauma centre and can receive trial intervention
3. Mechanism of injury blunt thoracic trauma
4. Radiographic evidence of 1 or more new traumatic rib fractures
5. Moderate or severe unilateral acute pain (defined as 11-point numerical rating scale (NRS) pain >4 when patient performing vital capacity breath or effective cough) at time of enrolment. Patients may have bilateral fractures, but pain must be unilateral

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Previous inclusion criteria:

1. 18 years and older.
2. New admission to major trauma centre and can receive trial intervention within 12 hours of admission
3. Mechanism of injury blunt thoracic trauma
4. Radiographic evidence of 1 or more new traumatic rib fractures
5. Moderate or severe unilateral acute pain (defined as 11-point numerical rating scale (NRS) pain >4 when patient performing vital capacity breath or effective cough) at time of enrolment. Patients may have bilateral fractures, but pain must be unilateral

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
27

Key exclusion criteria
Current exclusion criteria as of 05/10/2023:

1. Patient refusal or inability to give informed written consent for any reason
2. Thoracic injury requiring emergent operative or interventional radiology management
3. Allergy to local anaesthetic
4. Infection at site of ESP block
5. Actual or estimated total body weight 50kg or less thereby precluding safe dosing of local anaesthetic for ESP block

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Previous exclusion criteria:

1. Patient refusal or inability to give informed written consent for any reason
2. Thoracic injury requiring emergent operative or interventional radiology management
3. Allergy to local anaesthetic
4. Infection at site of ESP block
5. Actual or estimated total body weight 50 kg or less the,reby precluding safe dosing of local anaesthetic for ESP block.
6. Current or recent involvement in other clinical research

Date of first enrolment
01/07/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Manchester Royal Infirmary
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
The Royal London Hospital
Whitechapel Road
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London
United Kingdom
E1 1BB

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

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Derby Road
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Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from Dr David Hewson (david.hewson@nottingham.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	25/01/2022	08/03/2022	No	Yes
Participant information sheet	Participant information sheet summary version 1.2	21/02/2022	08/03/2022	No	Yes
Protocol article		21/09/2022	22/09/2022	Yes	No
Plain English results			24/06/2025	No	Yes