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A two-arm pragmatic randomised control trial comparing the clinical and cost-effectiveness of serratus anterior plane block (SAP) in reducing the rate of respiratory infections 5 days post randomisation in patients with multiple rib fractures (MRF) when compared with the usual care in the NHS trauma setting

Submission date 13/10/2022	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/10/2022	**Overall study status** Ongoing	
Last Edited 28/02/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims

People admitted to the hospital with multiple rib fractures often experience severe pain that reduces their coughing or movement. This leads to secretions building up in the lungs. As a result, it increases the risk of developing severe lung and blood infections, which delay recovery and hospital discharge, reduce quality of life after discharge and reduce the rate of survival. As part of the usual care, patients usually receive physiotherapy, deep breathing exercises (incentive spirometry) and rib fixation. Doctors would prescribe opiate-based pain relief to help patients to manage their pain, however this is often ineffective and comes with undesirable side effects.

ERASER aims to find out whether a regional pain relief technique, SAP (Serratus Anterior Plane block), used in addition with usual care, reduces the chance of developing lung infection, for people with multiple rib fractures. SAP is a technique where pain relief medication is infused into the chest at a regular interval, through a small tube (catheter) that is inserted from the side of the body under the guidance of ultrasound. This provides pain relief to the fracture area.

Who can participate?

Patients aged 16 years or older, with multiple rib fractures

What does the study involve?

Whilst in hospital, participants will be asked to rate the pain they are experiencing at regular intervals. The researchers will gather further data needed for this trial from the medical notes. A small blood sample will be taken for use in future research. After discharged from hospital, the

researchers will give participants a phone call at 1 and 3 months from when they joined the trial, to see the progress of recovery.

What are the possible benefits and risks of participating?
While there is no direct benefit or financial incentives to participants that take part in this trial, the information provided by participants may help in the long-term, to improve and shape future care for patients with multiple rib fractures.

SAP has been used across the NHS and has been shown to be relatively safe. However, as with most medical treatments, there are some uncommon risks associated with it, this includes possible infection or bleeding at to the site of catheter insertion, arrhythmias and nerve injury. The research team will closely monitor your health. If you have any concerns during your time in the trial, please do not hesitate to talk to the clinical care team or researcher team. There will be an independent safety committee that will review the trial data anonymously at regular intervals and on-demand where necessary to ensure that the trial is safe to continue.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
August 2021 to July 2026

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

Who is the main contact?
Dr Naveed Saeed, n.saeed@bham.ac.uk

Study website
https://www.birmingham.ac.uk/research/bctu/trials/portfolio-v/eraser/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307628

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53786, NIHR130632, IRAS 307628

Study information

Scientific Title
A pragmatic randomised controlled trial evaluating the clinical and cost-effectiveness of serratus anterior plane block with catheter insertion compared to usual care in patients with multiple rib fractures

Acronym
ERASER

Study objectives
SAP is more effective than usual care for the treatment of pain after multiple rib fractures (MRF) through improving clinical outcomes and cost-effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 11/11/2022, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8246; harrow.rec@hra.nhs.uk), ref: 22/LO/0607

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
Available from trial website

Health condition(s) or problem(s) studied
Multiple rib fractures

Interventions
Participant will be asked to rate their pain on a numerical scale and donate a blood sample for future research use.

Researchers will enter the baseline data in the secure online database and the computer will randomly assign the participant to receive SAP with usual care or usual care (at 1:1 ratio). A minimisation algorithm (built into the database) will be used to ensure balance in the intervention allocation over the following variables: Gender, Age, Centre, Injury Severity Score, Pulmonary contusion, Anatomical location of fracture, Presence of flail segment, and a random element (to avoid the possibility of allocation becoming predictable).

Due to the urgent nature of the condition, randomisation and intervention should occur on the same or next day after consent has been taken.

Participants will be asked to rate their pain on a numerical scale 4x a day on day 1-5, day 14 and on discharge from hospital.

Researchers will continue to collect follow up data from the medical notes until participant is discharged from the hospital. At month 1 and 3 from randomisation, the researcher will give a telephone call to the participant to monitor their progress of recovery. They will be asked to rate their quality of life (EQ-5D-5L) and confirm if they have used any community care resources for the same injury. They will also be asked to rate their pain (MRC dyspnoea scale, Brief Pain Index, McGill Pain Questionnaire).

Intervention Type

Procedure/Surgery

Primary outcome measure
New diagnosis of pneumonia, as agreed by a blinded end point assessment committee, five days after randomisation

Secondary outcome measures
1. Pain assessed using a numerical rating scale (0-10), recorded every 4 hours, day 1 to 5, day 14 and before discharge, and by the patient-reported BPI at one and three-months post-randomisation.
2. Ventilatory function measured by incentive spirometry and peak expiratory flow twice a day via the daily assessment log until discharge
3. Number of days ventilated and the requirement for invasive/non-invasive methods
4. 30 day and 3 month mortality
5. Complications and safety data associated with SAP
6. Opiate consumption such as morphine and related compounds (daily until discharge and at 1 and 3 months post randomisation)
7. Length of stay in hospital and critical care level two/three facility
8. Hospital re-admission within 30 days of discharge
9. Patient-Reported Outcome Measures (PROMs) at 1 and 3 months:
9.1. Qulaity of life: EQ-5D-5L
9.2. Medical Research Council (MRC) dyspnoea scale at 3 months only
9.3. Brief Pain Index (BPI)
9.4. McGill Pain Questionnaire (SF-MPQ-2)

Overall study start date
01/08/2021

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Patients >=16 years with unilateral or bilateral >=3 rib fractures following blunt chest trauma
2. Injury occurred <=72 hours of hospital admission

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants

Planned Sample Size: 824; UK Sample Size: 824

Key exclusion criteria
1. Severe traumatic brain injury with a predicted ventilatory requirement >7 days
2. Acute quadriparesis
3. Spinal fracture precluding mobilisation
4. Penetrating trauma or open rib fractures
5. Upper airway injury requiring intubation and mechanical ventilation with an expected dependency of more than 5 days (e.g. tracheal disruption)
6. Any chest wall injuries that preclude a catheter insertion
7. Not anticipated to survive >= 48 hours
8. Contamination or infection at site of potential SAP insertion
9. Any contraindication for the treating clinician for SAP block catheter insertion
10. Patients of childbearing age who have tested positive for pregnancy

Date of first enrolment
01/02/2023

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
Walsgrave General Hospital
Coventry and Warwickshire NHS Trust
Clifford Bridge Road
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CV2 2DX

Study participating centre

Queen's Medical Centre
Nottingham University Hospitals NHS Trust
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Study participating centre
Royal Stoke University Hospital
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Sponsor type
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http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

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

Intention to publish date
30/07/2027

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No