

Pain control in older patients with rib fractures: A randomised feasibility trial of lidocaine patches

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| Submission date 15/04/2021 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 22/04/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 20/05/2024 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

We know that pain from broken ribs can be severe. Currently, to control the pain, strong pain killers, like morphine, are often used. These can cause side-effects like constipation and confusion in older people. We have identified that a patch containing a numbing medication (anaesthetic) called lidocaine, put on the skin over the broken ribs very soon after injury, may help to control pain and improve breathing with fewer side effects. Older people are likely to benefit most from these patches but there is no research to support this.

In this small study we hope to find out whether a larger study could work by seeing how many patients are willing to take part and whether the information we collect is complete. We will also see if patients get chest infections or medication side-effects in the 30-days after injury, to see whether the patches could help.

Who can participate?

We are looking for about 100 older people (aged 65 years or older) in the Emergency Department, who are found to have broken ribs, and who need admission to a hospital ward.

What does the study involve?

To join the study, patients will be asked to complete a consent form confirming their agreement to take part, and a questionnaire which will ask about their general health, pain severity, and have their mobility assessed. In some cases, if a patient is unable to complete a consent form themselves, we will ask a personal representative (such as a carer or relative) on their behalf.

Participants will be allocated to one of two treatment groups through a process called randomisation (i.e. they will have an equal chance of receiving either treatment); half of the participants will be in one group and half in the other. In one group, patients will have pain killers (like paracetamol and/or morphine) prescribed in the usual way and their usual treatment will not change ("Usual Care" group). In the other group, patients will have pain killers (like paracetamol and/or morphine) prescribed in the usual way. In addition, they will have a patch

containing numbing medication placed over their broken ribs. This treatment will start in the Emergency Department and last for 3 days, or until they are discharged from hospital, whichever is sooner ("Usual Care + Lidocaine Patch" group).

Participants will be monitored closely for the next 3 days (or until time of discharge if sooner), including measuring pain severity every 4 hours (not if they are asleep), levels of confusion, mobility, and overall health.

At 30 days, participants will be asked to complete a final questionnaire about their health and wellbeing. They may also be asked if they would be happy to talk to a researcher by telephone about their experiences of taking part in the study; this is optional. Researchers will also look at participant's medical records to monitor their health over the 30 days. This will be the end of the study.

What are the possible benefits and risks of participating?

Possible benefits. Some patients may have improved pain if they have the lidocaine patches put over the broken ribs. If this is the case, it may help more patients in future. We are unable to offer any payment or expenses for taking part in the main study.

Possible disadvantages or risks. Lidocaine patches have been shown to be very safe and some specialist pain doctors already use them. Very rarely, the patch can irritate the skin. If this happens, the patch will be removed.

Where is the study run from?

The study will take place in (at least) three NHS Emergency Departments in the UK ("research sites").

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

January 2020 to March 2023

Who is funding the study?

Dr Edward Carlton, Advanced Fellowship NIHR300068, is funded by the National Institute for Health and Care Research (NIHR) for this research project. The views expressed are those of the author(s) and not necessarily those of the NIHR, NHS or the UK Department of Health and Social Care.

Who is the main contact?

RELIEF Central Study Office (Trial Manager), relief-trial@bristol.ac.uk

Study website

<https://relief.blogs.bristol.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

Dr Edward Carlton

ORCID ID

<http://orcid.org/0000-0002-2064-4618>

Contact details

Emergency Department
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Bristol
United Kingdom
BS10 5NB
+44 (0)7595 040112
Ed.Carlton@nbt.nhs.uk

Type(s)

Public

Contact name

Dr Madeleine Clout

ORCID ID

<http://orcid.org/0000-0001-7645-1199>

Contact details

RELIEF Central Study Office
Bristol Trials Centre (BRTC)
Bristol Medical School
University of Bristol
Canynges Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS
+44 (0)117 455 2187
relief-trial@bristol.ac.uk

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

285096

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 48195, IRAS 285096

Study information

Scientific Title

The Randomised Evaluation of early topical Lidocaine patches in Elderly patients admitted to hospital with rib Fractures (RELIEF): feasibility trial

Acronym

RELIEF

Study objectives

We are assessing whether it is feasible to conduct a multi-centre randomised controlled trial (RCT) to evaluate the use of topical lidocaine patches in older hospitalised patients with rib fractures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 13/07/2021:

1. Approved 30/03/2021, South Central - Oxford C Research Ethics Committee (Health Research Authority, Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8241; oxfordc.rec@hra.nhs.uk), ref: 21/SC/0019
2. Approved 08/07/2021 in relation to Adults with Incapacity (Scotland) Act 2000, Scotland A Research Ethics Committee (NHS Lothian, Waverley Gate, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG; +44 (0)131465 5680; Manx.Neill@nhslothian.scot.nhs.uk), ref: 21/SS/0043

Previous ethics approval:

Approved 30/03/2021, South Central - Oxford C Research Ethics Committee (Health Research Authority, Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8241; oxfordc.rec@hra.nhs.uk), ref: 21/SC/0019

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

Participant information sheets will be made available on our study website (<https://relief.blogs.bristol.ac.uk/>). Alternatively, please use the contact details below to request a copy of the appropriate participant information sheet(s).

Health condition(s) or problem(s) studied

Elderly patients admitted to hospital with rib fractures

Interventions

Patients will be randomised on a 1:1 ratio to either the lidocaine patch (intervention) or standard care (control) group immediately after diagnosis in the Emergency Department and written consent is obtained.

Intervention: Patients randomised to the intervention group will have up to 3 x 700mg lidocaine patch(es) (Ralvo®) applied over the most painful area of rib injury after first diagnosis as soon as practical within the Emergency Department. The patches will be applied once daily for 12 hours in accordance with the manufacturer's (Grünenthal) instructions, followed by a 12-hour patch-free period. Treatment will continue for up to 72 hours or until the time of discharge, whichever is sooner. The intervention is additive to standard clinical management, described below.

Control (standard clinical management): All patients regardless of randomised treatment allocation will receive standardised treatment according to local analgesic guidelines for patients with rib fractures. This should include prescription of regular paracetamol, ibuprofen (unless contraindicated) and codeine phosphate (or alternative weak opioid).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lidocaine patch

Primary outcome measure

Feasibility Outcomes

1. Number of eligible patients approached is measured using study-specific screening log records throughout the trial recruitment period.
2. Proportion of approached patients that are randomised is measured using study-specific screening log, and randomisation, records throughout the trial recruitment period.
3. Attrition of participants (including both failure to complete the trial protocol and loss to follow up) is measured using research data and withdrawal records collected throughout the trial (i.e. until end of data collection).
4. Proportion of recruited patients for which the primary outcome is available and completeness of each secondary outcome measure is measured using research data collected throughout the trial (i.e. until end of data collection).

Secondary outcome measures

1. 30-day pulmonary complications are measured using patient records up to 30-day follow up.
2. Incidence of frailty syndromes / analgesia side-effects are measured using patient records to include, immobility, delirium, and constipation evaluated during the 72-hour intervention period and functional decline at discharge. Measures include the Rockwood Clinical Frailty Scale, Timed Up and Go Test, The 4-AT and Bristol Stool Chart. Development of acute delirium during inpatient stay also at 30-days (single item question).
3. All-cause mortality is measured using patient records up to 30-day follow up.
4. Intensive Care admission and length of stay are measured using patient records up to 30-day follow up.

5. Hospital re-admission within 30-days is measured using patient records up to 30-day follow up.
6. Total length of hospital stay is measured using patient records up to 30-day follow up.
7. Total opioid consumption in first 72-hours of admission is recorded from the prescribed medication administered as recorded on the patient's ambulance care record, Emergency Department drug chart or inpatient drug chart during the first 72 hours of attendance.
8. Total pain experienced over the 72-hours period are measured using the Visual Analogue Scale (VAS), and the Abbey pain scale over the 72-hour intervention period.
9. Health economic scoping is measured by the EQ-5D-5L questionnaire at baseline (retrospective pre-injury and post injury) and 30-days. The ICECAP-O and Chest Trauma Score (RibPROM) questionnaires at 30-days. Plus, information on key costs such as length of stay, intensive care use and medication prescribing will be recorded from patient records up to 30-day follow up.

Overall study start date

01/01/2020

Completion date

31/03/2023

Eligibility

Key inclusion criteria

Potential participants must satisfy the following criteria to be enrolled in this study:

1. Older adult patients (age ≥ 65 years)
2. Presenting to the ED with traumatic rib fracture(s) (including multiple fractures, flail chest and traumatic haemo/pneumothorax even if this requires intercostal chest drainage), confirmed radiologically (by chest X-Ray or CT scan conducted as part of routine care)
3. Requiring hospital admission for ongoing care

Participant type(s)

Patient

Age group

Adult

Lower age limit

65 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

Total final enrolment

100

Key exclusion criteria

Potential participants who meet any of the following criteria will be excluded from participation:

1. Serious distracting trauma to other body regions (adjudicated by the treating clinician):

examples include but may not be limited to: traumatic brain injury with cognitive impairment, acute spinal column fracture or spinal cord injury, abdominal and lower limb injuries requiring surgery, unstable pelvic fracture

2. Requirement for intubation and mechanical ventilation either prehospitally or in the ED
3. History of allergy to lidocaine
4. Open wounds at the site of patch application
5. End-stage dementia (adjudicated by the treating clinician, e.g. bed-bound and non-verbal); patients with mild to moderate cognitive impairment can be approached
6. End-stage liver failure with jaundice
7. End-stage heart failure with breathlessness at rest prior to injury
8. Those unable to communicate in the English language where all reasonable attempts to source translation services are exhausted within the ED
9. Patients transferred from non-recruiting units to a recruiting site who have a lidocaine patch applied as part of standard care prior to arrival in the recruiting site

Date of first enrolment

08/10/2021

Date of final enrolment

07/10/2022

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Southmead Hospital

North Bristol NHS Trust

Southmead Road

Westbury-on-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre

Derriford Hospital

Derriford Road

Crownhill

Plymouth

United Kingdom

PL6 8DH

Study participating centre

Musgrove Park Hospital

Taunton & Somerset NHS Foundation Trust
Parkfield Drive
Taunton
United Kingdom
TA1 5DA

Study participating centre

Royal Devon and Exeter Hospital

Royal Devon and Exeter NHS Hospital Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre

Royal Infirmary of Edinburgh

NHS Lothian
2 - 4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

Queen Elizabeth University Hospital

NHS Greater Glasgow and Clyde
Glasgow
United Kingdom
G12 0XH

Study participating centre

St George's Hospital

St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Sponsor information

Organisation

North Bristol NHS Trust

Sponsor details

Research & Innovation North Bristol NHS Trust
Floor 3 Learning & Research Building
Southmead Hospital
Westbury-on-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 414 9330
researchsponsor@nbt.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.nbt.nhs.uk/>

ROR

<https://ror.org/036x6gt55>

Funder(s)

Funder type

Government

Funder Name

NIHR Advanced Fellowship; Grant Codes: NIHR300068

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 19/12/2023:

Once results are available, we aim to publish a primary, peer-reviewed manuscript in a relevant medical journal, published as Open Access, with additional qualitative analyses described in specialty journals. Primary findings will also be presented at key meetings, e.g. the Annual Conference of the Royal College of Emergency Medicine, the European Society of Emergency Medicine Congress. A summary of results has been provided to participants via a newsletter and,

following publication, the paper will be made available to participants and the wider public via our trial website.
A full fellowship report for the NIHR has been completed.

Previous publication and dissemination plan:
Once results are available, we aim to publish a primary, peer-reviewed manuscript in an emergency medical journal, published as open access, with additional qualitative analyses described in specialty journals. Primary findings will also be presented at key meetings (e.g. the Annual Conference of the Royal College of Emergency Medicine, the European Society of Emergency Medicine Congress) and made accessible to participants and the wider public via a newsletter and/or our study website.
We will also complete a full report for the NIHR.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Anonymous research data will be stored securely and kept for future analysis with participant consent. Data will be kept anonymous on the University of Bristol Research Data Storage Facility (RDSF, <https://www.bristol.ac.uk/acrc/research-data-storage-facility/>). Requests for access to data must be via a written confidentiality and data sharing agreement (DSA) available from the RDSF website which will be confirmed by the RELIEF Chief Investigator (or appointed nominee). The DSA should cover limitations of use, transfer to third parties, data storage and acknowledgements. The person applying for use of the data will be scrutinised for appropriate eligibility by members of the research team. The approved Consent Form for the study includes the statement “I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.”

IPD sharing plan summary
Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------------|-------------|--------------|------------|----------------|-----------------|
| Protocol file | version 4.0 | 04/03/2022 | 09/09/2022 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Protocol article | v1 | 27/07/2023 | 01/08/2023 | Yes | No |
| Plain English results | | | 07/08/2023 | No | Yes |
| Protocol article | v2 | 25/09/2023 | 26/10/2023 | Yes | No |
| Results article | | 16/05/2024 | 20/05/2024 | Yes | No |