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

Submission date
15/04/2021

Recruitment status
No longer recruiting

Registration date
22/04/2021

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
285096

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
65 years

Sex
All

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
United Kingdom

England

Scotland

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
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SW17 0QT

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
NIHR Advanced Fellowship; Grant Codes: NIHR300068

Results and Publications

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?
Results article		16/05/2024	20/05/2024	Yes	No
Protocol article	v1	27/07/2023	01/08/2023	Yes	No
Protocol article	v2	25/09/2023	26/10/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			07/08/2023	No	Yes
Protocol file	version 4.0	04/03/2022	09/09/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes