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

RECOVERED CAPACITY PARTICIPANT INFORMATION SHEET

(For use in Scotland only)

You are being invited to consider continuing to take part in a research study. It is important for you to understand why the research is being done and what it will involve. You are welcome to ask us any questions you may have. Thank you for taking the time to read this information.

Please note: *for the purpose of this information sheet, any reference to 'we' means the study Sponsor (North Bristol NHS Trust).*

Important things that you need to know

- **It is important that you understand** why you are already involved in this study, what the study is about, why it is being done, and what will be involved if you continue to take part.
- **Within this information sheet:**
  - **PART A:** explains why you are already involved in this study and why this study is being done;
  - **PART B:** describes what taking part involves; and
  - **PART C:** provides further general information about the study, including what will happen to your data if you take part.

PART A: Why is the study being done?

1. Why am I already in this study?

During your recent attendance to the Emergency Department because of an injury to your chest, you were unable to give consent for entry into this study. We therefore asked your Legal Representative (i.e. a Welfare Guardian or Welfare Attorney, or if not in place then your nearest relative), who advised that you would want to take part and provided consent on your behalf. This is permissible under the Adults with Incapacity (Scotland) Act 2000.

2. What is the purpose of the RELIEF study?

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. 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. **We think older people are likely to benefit most from these lidocaine patches but there is currently no research to support this.**

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

3. Why was I chosen to take part? Do I have to continue to take part?

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.

You recently attended the Emergency Department because of an injury to your chest. You were found to have broken ribs and the doctors looking after felt it would be best for you to stay in hospital. Although you were unable to give permission at the time, your Legal Representative advised that you

would want to take part and you were entered into the study in the Emergency Department. This was important because we need to understand whether the patches work very soon after injury. However, it is now felt that you are able to make a decision about whether you wish to continue in the study, or not. It is up to you to decide whether to continue taking part. If you decide not to continue taking part, your usual care will not be affected in any way.

PART B: What does taking part in the study involve?

4. What will happen to me if I agree to take part?

The **diagram on the next page** summarises what is (was) involved, from being invited to join through to the end of the study. More information about what the study involves is shown below, and on the pages that follow.

It was important to include you right at the beginning of the study because we need to know whether patches work very soon after injury. You may therefore have already had the patches applied (or not). Given you are now able to make a decision about your ongoing participation in the study, we are asking permission to use the information collected about you (and to continue collecting information, where relevant) rather than to decide to have the patches again.

(A) Prior to you regaining capacity to make an informed decision for yourself:

- A doctor or nurse asked a Legal Representative to complete a study consent form confirming their understanding of the study and agreement for you to take part. They were given a study information pack to keep, as well as a copy of their completed consent form.
- You were allocated to one of two treatment groups (either "**Usual Pain Relief"** or "**Usual Pain Relief + Lidocaine Patch"**) through a process called randomisation.* Half of the participants in this study will be in one group and half in the other.

USUAL CARE: you will have had pain killers (like paracetamol and/or morphine) prescribed in the usual way and your usual treatment will not change.

USUAL CARE + LIDOCAINE PATCH: you will have had pain killers (like paracetamol and/or morphine) prescribed in the usual way. In addition, you will have had a patch containing numbing medication called lidocaine placed over your broken ribs. This treatment was started in the Emergency Department and lasts for 3 days, or until the time of discharge if sooner.

- After you were allocated to a treatment group, you were enrolled in the study. One of the research team collected some information from you (and/or your Legal Representative) about your general health and, if you were able, assessed your mobility.
- A study-specific prescription was then authorised, and the medication administered in the hospital.

***Randomisation** means you will have an equal chance of receiving either treatment. Randomisation is used as it creates groups of participants that are similar except for the medication they are allocated. This will enable a fair comparison of the two groups so that at the end of the study we can reliably assess any differences. If you or someone in the study were allowed to choose the medication, the groups of people being compared may not be sufficiently similar.*

(B) After you regain capacity to make an informed decision for yourself:

- A doctor or nurse will ask you to complete a consent form confirming your understanding of the study and agreement to continue to take part (this may be via telephone or face-to-face where feasible). You will be given this information sheet to keep, as well as a copy of your completed consent form.

Flow diagram for the RELIEF study

Initial Invitation to Take Part

A Legal Representative discussed/read supporting information materials with a doctor or nurse and asked any questions. Your Legal Representative advised that you would want to take part. So:

- your Legal Representative completed an informed consent form
- you (and/or your Legal Representative) were asked to complete study questionnaires and other study data collection
- you were allocated to one of two study treatment groups by a process called randomisation.

Randomisation

USUAL CARE **OR** **USUAL CARE + LIDOCAINE PATCH**

Treatment

For those in the "Usual Care" group: you will have had pain killers (like paracetamol and/or morphine) prescribed in the usual way and your usual treatment will not change.

For those in the "Usual Care + Lidocaine Patch" group: you will have had pain killers (like paracetamol and/or morphine) prescribed in the usual way. **In addition**, you will have had a patch containing numbing medication called lidocaine placed over your broken ribs. This treatment was started in the Emergency Department and will last for 3 days, or until the time of discharge if sooner.

Follow Up – First 3 Days (or until discharged if sooner)

A member of the research team will have:

- asked you to record how severe your pain is every four hours (not if you are asleep)
- monitored you to see if you became confused
- have had your mobility assessed.

Follow Up – 30 Days After Injury

A member of the research team will:

- contact you to complete a questionnaire about your health and wellbeing. ***For most people, their direct involvement in the study ends at this point.***
- look at your medical records to monitor your health and see if you develop a chest infection or side-effects from medications over the 30 days.

We may ask if you would be happy to talk to a researcher by telephone about your experiences of taking part in the study. ***Only a few people are needed for these interviews and they are completely optional.***

WHEN YOU REGAIN CONSENT (WHICH MAY OCCUR AT ANY TIME DURING THE STUDY)

- A member of the research team will discuss/ask you to read this information sheet. Ask any questions.
- **If you agree to continue taking part**: you will be asked to complete an informed consent form and continue to participate.
- **If you do not want to continue taking part:** you will be withdrawn from the study. We will keep any information (data) collected about you up until this point unless you request that we do not.

5. What else is involved in the study?

This depends on how long you stay in hospital.

NB: *Some of the following points may have already taken place, depending on when you regained capacity.*

- **For the first 3 days** a member of the research team will ask you to record how severe your pain is every four hours; if you are asleep, we will not wake you up to do this. You will also be monitored to see if you become confused and to have your mobility assessed.
- **Around 30 days after your injury**, a researcher will contact you and ask you to complete a final questionnaire about your health and wellbeing. A researcher(s) will also look at relevant parts of your medical records to see if you develop a chest infection or side-effects from any medications over the 30 days. For most people, involvement in the study ends at this point.
- You may also be asked if you would be happy to talk to a researcher by telephone within the next few weeks, about your experiences of taking part in the study. *Only a few people are needed for these interviews and they are completely optional.*

6. What happens if I have the patch put on my broken ribs?

It is really important to know that you can still ask for stronger pain killers if the patch does not help your pain or if the patch treatment has finished. In some cases, you may be seen by a pain specialist who will discuss your pain relief options with you.

7. What happens if I do not have the patch put on my broken ribs?

Your usual care will not change. You can discuss your pain relief options with your clinical team. In some cases, you may also be seen by a pain specialist (who may still prescribe a patch).

8. What are the possible benefits and disadvantages or risks of taking part in this study?

Benefits. Some patients may have improved pain if they have the 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 study.

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, please let the doctors looking after you know and the patch will be removed.

9. Will my GP be informed?

Your GP (GP Practice) will be informed by letter that you are taking part in the study. A copy of your completed consent form will also be included. This is done so they know your treatment may have been altered and that we may access your medical records where it is relevant to this study.

10. If I take part, can I change my mind and leave the study?

Yes. You can withdraw from the study at any time without giving a reason, and your medical care and legal rights will not be affected.

If you just want to stop having the lidocaine patch applied, it will still be very valuable if you complete future questionnaires/assessments, or at least allow us to continue to access relevant sections of your medical notes. It is very important that we try and get results from everyone who took part in the study, whether they continued with the medication or not.

If you wish to completely withdraw, we will confidentially keep any information (data) collected about you up until the point of withdrawal, to use in our analysis of the study results, unless you specifically request that we do not.

11. What if something goes wrong?

If you are unhappy about any aspect of this study, the doctor or nurse attending you on the ward will do their best to address your concerns and/or answer your questions.

In the unlikely event that something does go wrong, and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against North Bristol NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

12. Will my taking part in this study be kept confidential?

Yes, all information collected about you during the study will be kept strictly confidential. Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR).

Relevant sections of your medical notes and information collected during the study may be looked at by authorised individuals from the Sponsor organisation or its representatives, University of Bristol, your local NHS Trust and the regulatory authorities, where it is relevant to you taking part in this research. North Bristol NHS Trust and the University of Bristol will act as joint data controllers for this study. This means that we are both responsible for looking after your information and using it properly. Personal information such as your name, email address and phone number will be stored on a secure database with the central research team (University of Bristol). The University of Bristol, on behalf of North Bristol NHS Trust (Sponsor), will keep identifiable information about you for at least 5 years after the study has finished.

PART C: Further information about the study and what will happen to your data if you take part

13. How will we use information about you?

We will need to use information from you and/or from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name
- Gender
- Ethnicity
- Date of birth
- Contact details (for example: postcode, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Some of your information will be sent to "Sealed Envelope™". This is the company that provide the randomisation software which helps to enable the process of treatment allocation. Your local researcher will provide "Sealed Envelope™" with relevant information about you to enable the randomisation process. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

14. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have (unless you specifically request for this to be withdrawn).
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and/or your hospital. If you do not want this to happen, tell us and we will stop.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

15. Where can you find out more about how your information is used?

- You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients/
- our leaflet "How we use information from patients" available from: relief.blogs.bristol.ac.uk
- at the University of Bristol website: www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- at North Bristol NHS Trust website: www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
- by contacting North Bristol NHS Trust's Head of Information Governance: helen.williamson@nbt.nhs.uk
- by asking one of the research team: see last page
- by sending an email to: relief-trial@bristol.ac.uk, or by ringing us on 0117 331 3907.

16. What will happen to the results of the research study?

We aim to complete this research in 2023 and once available, results will be published in a medical journal(s) and presented at conferences attended by healthcare professionals and specialists. Results will also be made accessible to participants and the wider public via a newsletter and/or our website. If this small study is successful, we will use the information we collect, to carry out a larger study. **You will not be personally identified in any report/publication.**

17. Can the study information be used to help with other research?

It is important that good quality research data can be shared with others to advance clinical research and benefit patients in the future. After the end of the study, **anonymised** information collected during the study *may* be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

18. Have patients and the public been involved in the study?

Yes. Patient volunteers have helped us design this research and continue to be involved in all aspects.

19. Who is organising the research? Who has reviewed the study?

Doctors and researchers from North Bristol NHS Trust and the University of Bristol are leading this research. The study is funded by a grant awarded by the National Institute for Health Research. Your doctors will not be paid for including you in this study. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by 'Scotland A Research Ethics Committee' (reference 21/SS/0043), 'South Central – Oxford C' Research Ethics Committee (reference 21/SC/0019) and the Health Research Authority. An independent Trial Steering Committee will monitor the study to ensure it is conducted according to good research practice.

THANK YOU FOR READING THIS INFORMATION SHEET. PLEASE KEEP A COPY FOR YOUR RECORDS.

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RELIEF STUDY TEAM CONTACT DETAILS

LOCAL (HOSPITAL) RESEARCH TEAM

Local Principal Investigator(s): [insert name]

Local Research Nurse(s): [insert name]

Local Contact Details: [insert as appropriate, e.g. telephone number, address]

Local PALS Contact Details: [insert details]

STUDY OFFICE (University of Bristol)

Trial Manager: Dr Amanda Lewis

Chief Investigator: Dr Edward Carlton

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Telephone: 0117 331 3907

Study website: relief.blogs.bristol.ac.uk

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