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

PARTICIPANT INFORMATION SHEET - SUMMARY

You are being invited to take part in a research study. Before you decide, 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.

We are inviting older people (aged 65 years or older) who are found to have broken ribs, and who need admission to a hospital ward, to take part in a research study known as "RELIEF".

- 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.** However, there is currently no research to support this.
- **We want to find out if it is feasible to conduct a study exploring the use of lidocaine patches as a means of pain control for rib fractures.** We also want to monitor the health and wellbeing of these patients 30 days after injury.
- **If you join the study**, you will be asked to complete a consent form confirming your agreement to take part, and a questionnaire which will ask about your general health, pain severity, and have your mobility assessed.
- You will be allocated to receive either **"USUAL PAIN RELIEF"** (like paracetamol and/or morphine), or **"USUAL PAIN RELIEF PLUS A LIDOCAINE PATCH"**, through a process called randomisation (i.e. you will have an equal chance of receiving either treatment)**.** The patch will be placed over your broken ribs for up to 3 days or until the time of discharge, whichever is sooner. The patches are very safe and some pain doctors already use them. Very rarely, the patch can irritate the skin. You **can still ask for stronger pain killers if the patch does not help,** and you may be seen by a pain specialist who will discuss available pain relief options with you.
- **You 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 you are asleep), levels of confusion, mobility, and overall health.
- **At 30 days**, you will be asked to complete a final questionnaire about your health and wellbeing. You may also be asked if you would be happy to talk to a researcher by telephone about your experiences of taking part in the study; this is optional. Researchers will also look at your medical records to monitor your health over the 30 days. This will be the end of the study.
- By taking part in this study, **you will help to demonstrate whether a larger study is feasible to explore whether patients who have patches put over their broken ribs may have improved pain.** This may influence the treatment of patients in the future.
- The **diagram over the next page summarises what is involved if you take part**. The doctor or nurse will be happy to answer any questions you may have about the study and can provide an additional information pack for you to read now or later.
- **Taking part is entirely voluntary.** If you take part, you can leave the study at any time without giving a reason. Your treatment will continue as normal.

Use of personal data

In this research study we will use information from you, your medical records, and/or your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and/or use it for future research. We will make sure no-one can work out who you are from the reports we write. The additional information pack tells you more about this.

Flow diagram for the RELIEF study

Invitation to Take Part

Read this Summary Information Sheet. Ask any questions. Read the additional Information Pack (now or later).

Eligibility Screening

The doctor or nurse looking after you will check to see if it is suitable for you to take part in the study, or not. **If it is suitable for you to take part and you want to, you will be:**

- asked to complete an informed consent form
- asked to complete study questionnaires and other study data collection
- 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 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 pain killers (like paracetamol and/or morphine) prescribed in the usual way. **In addition**, you will have a patch containing numbing medication called lidocaine placed over your broken ribs. This treatment will be 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:

- ask you to record how severe your pain is every four hours (not if you are asleep)
- monitor you to see if you become confused
- have 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.***

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