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

WELFARE GUARDIAN / WELFARE ATTORNEY / NEAREST RELATIVE INFORMATION SHEET - SUMMARY

You are being invited to consider giving your permission for your ward/relative/person you are consenting on behalf of* to take part in a research study known as "RELIEF". 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. Please keep a copy for your records.

For the purpose of this Summary Information Sheet, they are herein referred to as "relative".

- 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 in older people (aged 65 years or older).** We also want to monitor the health and wellbeing of these patients 30 days after injury.
- **If you agree for your relative to take part,** you will be asked to complete a consent form (over the telephone, or face-to-face where feasible) confirming that they would want to take part in the study. You will also be asked to confirm whether you are willing to support them complete questionnaires about their health and wellbeing (at the beginning and 30 days later), or not; your relative can still take part if you decline to help complete the questionnaires.
- Your relative 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. they will have an equal chance of receiving either treatment)**.** The patch will be placed over their 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/they **can still ask for stronger pain killers if the patch does not help,** and they may be seen by a pain specialist who will discuss available pain relief options with you both.
- **Your relative 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**, your relative will be asked to complete a final questionnaire about their health and wellbeing (and you may need to offer support, if you previously agreed). Researchers will also look at their medical records to monitor their health over the 30 days. 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. This will be the study end.
- 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 on the next page summarises what is involved if your relative joins the study**. 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.** We ask that you put your own views about the research aside and to consider, and take into account, the past and present wishes and feelings of your relative had they been able to consent for themselves. If you decide they should take part, you and relative can leave the study at any time without giving a reason. Their treatment will continue as normal. If you do not want to take on the responsibility of providing consent on behalf of your relative, we understand.

Dr Edward Carlton is funded by a National Institute for Health Research (NIHR), Advanced Fellowship (NIHR300068) for this research project. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. This study was designed and delivered in collaboration with the Bristol Randomised Trials Collaboration (BRTC), a UKCRC registered clinical trials unit which, as part of the Bristol Trials Centre, is in receipt of National Institute for Health Research CTU support funding. This study is sponsored by North Bristol NHS Trust.

Use of personal data

In this research study we will use information from you. 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

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

Eligibility Screening

The doctor or nurse looking after your relative will check to see if it is suitable for them to take part in the study, or not. **If it is suitable for them to take part and you agree on their behalf, you will be:**

- asked to complete a Consent Form (over the telephone, or face-to-face where feasible)
- asked to help your relative complete study questionnaires and/or other study procedures/data collection; this is optional for you as a Welfare Guardian/Attorney/Nearest Relative.
- Your relative will be 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: your relative will have pain killers (like paracetamol and/or morphine) prescribed in the usual way and their usual treatment will not change.

For those in the "Usual Care + Lidocaine Patch" group: your relative will have pain killers (like paracetamol and/or morphine) prescribed in the usual way. **In addition**, they will have a patch containing numbing medication called lidocaine placed over their 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 your relative to record how severe their pain is every four hours (not if they are asleep or it is unfeasible)
- monitor them to see if they become confused and assess their mobility (where feasible).

Follow Up – 30 Days After Injury

A member of the research team will:

- Ask your relative to complete a questionnaire about their health and wellbeing. You may be asked to support them if you previously agreed. ***For most people, this will be the end of their study involvement.***
- look at your relative's medical records to monitor their health and see if they 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.***