

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

CONSULTEE INFORMATION SHEET - SUMMARY

We would like to invite you to become a Personal (or Nominated) Consultee regarding your relative/friend who is unable to decide for themselves whether they would like 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.

- 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 to be a Consultee,** you will be asked to complete a declaration form (over the telephone, or face-to-face where feasible) advising whether your relative/friend would want to take part in the study, or not.
- **If you advise that they would like to take part,** you will also be asked to confirm whether you are willing to support your relative/friend complete questionnaires about their health and wellbeing (at the beginning and 30 days later), or not; your friend/relative can still take part if you decline to help complete the questionnaires.
- Your relative/friend 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/friend 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/friend 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 over the next page summarises what is involved if you and your relative/friend takes 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 and your relative/friend 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 being a Consultee, we understand. We will approach someone else where possible.

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