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ESPER
Early Analgesia in Rib Fractures Trial

Erector Spinae Plane blocks for the Early Analgesia of Rib fractures in trauma: A multicentre pilot randomised controlled trial with feasibility and embedded qualitative assessment.

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1. What is the purpose of the study?

Currently if you break your ribs doctors will try to give the best pain relief with different medicines. These may include tablets, strong painkillers in a drip, epidural injections and even surgery. Physiotherapy and careful nursing care is also important however it may be different for each person as to what works best.

This study is looking to test if a new method of pain relief - called an erector spinae plane (ESP) block - can help people with broken ribs get better pain relief and reduce their risk of getting chest problems as a result of their broken ribs. ESP blocks are injections, like an epidural that use local anaesthetic to numb the nerves near the ribs. We know they help people after operations but we don't know if they can help with reducing pain after broken ribs and reducing the risk of getting a chest infection.

To test ESP blocks properly we need to do a large clinical trial at lots of hospitals with lots of patients. Before we do that we need to do a feasibility study to see if it is possible. We are asking you to take part in the feasibility study. This feasibility study will run at three UK hospitals in Nottingham, Oxford and London. We will collect data (for example pain scores) and you may also be asked to do an interview which will help us design a well thought-out large trial. If this feasibility study works, we will ask for NHS support for a larger trial within 12 months of finishing this project.

This study is called a randomised controlled trial because we need to compare different treatments between groups of patients. Each patient is put into a group by chance (randomly). You have a 50/50 chance of receiving either the treatment or placebo. The results are then compared. It is called a 'blinded' trial because you will not know which treatment group you are in.

2. Who has reviewed this study?

Research in the NHS is usually looked at by an independent group called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS, South Central - Oxford B Research Ethics Committee Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the 'Sponsor' (i.e., the lead NHS hospital) for this research. The National Institute for Health Research (NIHR) have funded this research.

3. Why have I been asked to take part?

a) Why have I been invited to take part?

You have been invited to take part because you have been admitted to hospital with broken ribs.

b) Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

If you withdraw, we will still keep records relating to the treatment given to you, up until the time you withdraw, as this is valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive.

4. What do I have to do?

a) What will happen to me if I take part in the study?

If you choose to take part in this study you will continue to be given pain relief for your rib fractures as part of the usual treatment provided by the hospital. In addition to this pain relief you will also be randomly (by chance) given either an injection of local anaesthetic into your back (called an ESP block) or a placebo (dummy) injection into your back. Although the doctor performing the injections will know which one you receive, you will not, and neither will the study team. This is called 'blinding' as it is important for us to be able to know whether the 'real' injection improves pain relief or not. The ESP block takes 5-10 minutes to complete by an anaesthetist, a doctor specialised in pain relief. They will ask you to either sit or lie on your side so they have access to your back. They will clean the skin on your back and look at the bones and muscles using an ultrasound machine. They will inject a small amount of local anaesthetic (numbing medicine) under the skin to help numb the skin. If you are randomly allocated to be given the ESP block, the doctor will then perform an injection under the skin, below a muscle in the back (called the erector spinae muscle).They will leave a flexible small tube of plastic in the skin (about the width of a piece of spaghetti) so that local anaesthetic medicine (numbing medicine) can continue to be trickled into your back for up to 3 days. If you are randomly allocated to be given the dummy ESP block, the doctor will then leave a flexible small tube of plastic on the skin (about the width of a piece of spaghetti) and connect this to a saline infusion using the same machine

as people in the ESP block group. Alongside the procedure you will continue to receive all 'usual' NHS medicines for rib fracture pain.

After the 6 week follow-up your involvement in the study will be complete. Because this is a feasibility study we would like to ask you questions about what taking part in the study was like – for example, whether there were there any problems or things you found difficult or feel should be changed but this is optional. This is really important feedback so we can design a larger trial in the future.

b) What do I have to do?

You will be asked about your pain, ability to cough and take deep breaths. We will also ask you to blow into a tube, called a spirometer, to assess how well you are breathing. We will look at how much oxygen you need and what other pain relief you need. The study team will visit you for the first 3 days after the ESP block (or dummy ESP block) alongside the clinical team. You will be visited at 3, 6, 9, 12, 24, 48 and 72 hours after joining the trial. At 72 hours the tube will be removed from your back and you will just receive standard care. We will then follow you up 6 weeks after the block to find out how the rest of your hospital stay was.

If you do decide to take part in the study, you must report any problems you have to your study nurse or doctor. There is more information on this in section 6. There is also a contact number given at the start of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

5. What are the possible benefits?

This may or may not help with your pain – that is the reason we are doing the study. There is no guarantee taking part in the research will benefit you, however you will be helping us understand this injury better and potentially improve care for patients in the future.

6. What are the disadvantages?

a) What are the side effects of any treatment received while taking part?

ESP blocks are already done as part of NHS care so we have a good understanding of their possible side effects. Common problems, side effects or complications are: the flexible tubing in your back muscle becoming dislodged and needing to be reinserted (estimated 1 in 10), bruising under the skin at the insertion site (1 in 10; this does not usually need any treatment). A rarer problem, side effect or complication is an overdose of local anaesthetic medicine (called local anaesthetic systemic toxicity (LAST); estimated 1 in 1,000). This is a possible complication whenever local anaesthetic medicine is used and ESP blocks are not thought to be any higher risk than other types of injection. The doctors and nurses looking after you for the study and your usual team know the signs and symptoms of LAST and will treat it with medicine if needed. Allergy to local anaesthetic medicine, the cleaning solution used to clean your back or the dressings used to dress your back after the injection is very rare, and again the doctors and nurses in the study know how to treat this rare complication, should it occur.

7. What will happen to my data?

a) Will my taking part in this study be kept confidential?

All the information about your participation in this study will be kept confidential. We will keep all information about you safe and secure.

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper, and electronically at your treating hospital, at Nottingham University Hospitals NHS Trust and at the University of Nottingham, under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

If you withdraw consent from further study treatment, your data and samples will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

b) Informing your General Practitioner (GP) or other healthcare professionals

With your permission your GP (and other doctors who may be treating you) may be notified that you are taking part in this study.

The information collected about you may also be shown to authorised people from the Health Research Authority and the independent Ethics Committee to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

c) Use of your personal data in research

We will need to use information from you and your medical records for this research project. This information will include your NHS number, name and contact details. People will use this information only 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.

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. 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.

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.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link www.nuh.nhs.uk/gdpr

By asking one of the research team or by visiting www.nuh.nhs.uk/gdpr

8. What happens if new information becomes available?

It is possible that during the course of this trial, new information becomes available about ESP blocks and rib fracture pain. If this happens while you are taking part in the trial, we will contact you to explain whether your participation in the trial can continue and in what form. If you are able to continue in the trial, you will be asked to sign an updated consent form, considering the new information. Regardless of whether you continue in the trial, you will continue to receive medical care, including pain relief, from the doctors treating you as part of usual NHS care.

9. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. Because this is a pilot study we would like to ask why you wanted to withdraw, although you do not have to answer this question, it would be helpful for us so we can design a better, larger trial in the future. Data already collected in the trial will be retained and analysed, but no further data will be collected once you withdraw.

10. What happens when the study is finished?

After the study is finished no further follow-up is required and you will not hear from us directly. The results of the study will be anonymised (so none of your personal details appear) and will be published in scientific journals and conferences. If you would like to see a copy of the study results you can contact the study team at ESPEAR@nuh.nhs.uk

11. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact the Patient Advice and Liaison Service (PALS) telephone 0800 183 0204.

In the event that something does go wrong and you are harmed during the research 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 but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

12. Further Information

You are encouraged to ask any questions you wish before, during or after your treatment. If you have any questions about the study please speak to your study nurse or doctor who will be able to provide you with up to date information about the study and ESP block procedure. If you require any further information or have any concerns while taking part in the study please contact your study nurse or doctor (both are listed at the top of this document).

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your medical notes, and one will be filed with the study records.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.