Conservative Management in Traumatic Pneumothoraces in the Emergency Department (CoMiTED): A Randomised Controlled Trial

DETAILED PARTICIPANT INFORMATION SHEET

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

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PART A: Why is the study being done?

You (the patient) are being invited 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. Thank you for taking the time to read this information.

If you have already read the Summary Participant Information Sheet and provided written informed consent, but on reading this more detailed information pack (now that you are more comfortable) you would like to amend (or withdraw) your consent, please speak with a member of the study team. More information about changing your mind is available in section 5 (page 5).

1. What is the purpose of the CoMiTED study?

A collapsed lung (also known as a 'pneumothorax') can occur following trauma such as falls, road traffic accidents or knife injuries. We are doing a study to compare different treatment options for a collapsed lung. Currently, doctors treat this condition by inserting a tube (chest drain) through the chest wall, to help the lung re-inflate. Every year, around 25,000 patients in England and Wales have a chest drain inserted. We think that more patients with a collapsed lung could be safely treated without a chest drain, but there is currently no good research evidence one way or the other. The National Institute for Health Research (NIHR) identified this as an area of need and funded our research study to answer the question.

Both treatments for a collapsed lung (treatment with or without a chest drain) have advantages and disadvantages, but we do not know if one is better than the other. This research will help us find out which treatment is better and whether doctors should change their practice and potentially treat fewer patients with a chest drain.

2. Is it suitable for me to take part?

We are looking for 750 participants (aged 16 years or older) who have been admitted to Accident and Emergency department (A&E), with a collapsed lung due to injury, to take part in our research.

You came to the A&E department because of an injury. You have been found to have a collapsed lung and it *may* be suitable for you to take part in the study. It is up to you whether you would like to take part, or not. If you decide not to take part, your usual care will not be affected in any way.

The study is not suitable for you to take part in if:

- Your doctors think a chest drain is definitely needed, or think it is unsafe for you to take part
- You are under 16 years old.

PART B of this information sheet explains what taking part in this study involves. Please continue over the page for more information.

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

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

- A healthcare professional will ask you to complete a form (known as a consent form) confirming you understand the study and agree to take part. You will be given a summary information sheet, this more detailed information sheet and a copy of your completed consent form to keep.
- You will then be put into one of two groups. One group will have treatment with a chest drain (current usual care; Group 1) and the other group will be treated without a chest drain to start with (Group 2).

GROUP 1 - TREATMENT WITH CHEST DRAIN (CURRENT USUAL CARE): you will have a chest drain inserted in A&E. The details of this procedure will be discussed with you by your clinician. After the procedure, you will be admitted to a suitable hospital ward and carefully monitored for ongoing treatment needs.

GROUP 2 - TREATMENT WITHOUT CHEST DRAIN: you will be treated without having a chest drain inserted in A&E. You will be admitted to a suitable hospital ward and be carefully monitored by your medical team who will offer appropriate treatment for your injury, which may include a chest drain at a later stage.

- To make sure the two groups are the same, you will be put into a group randomly, so that you have an equal chance of receiving either treatment. No one will be able to predict which group you will be in.
- You will have an equal chance of receiving either treatment. All participants will be assessed, have any other injuries treated, be given pain relief, and be monitored according to usual care of this hospital. You should not need to undergo any extra tests or spend any extra time in hospital as a result of taking part in this study.
- After you have been allocated to a treatment group, a member of the research team will collect some information about you, your general health, your injuries and medical treatments from your medical records.
- If you can, we will also ask you to complete a questionnaire about your health and wellbeing; this could happen up to 7 days after you join the study. We may ask a patient representative (such as your partner or a family member) some of this information on your behalf, if you are too unwell to do this.

2. What else is involved in the study?

- **Around 30 days after you join the study:** a researcher will ask you to complete a questionnaire about your health and wellbeing.
- A researcher will also look at relevant parts of your medical records to see if you have any further treatments or complications, and to record details of your care (e.g., how long you stayed in hospital).
- **Around 3 and 6 months after you join the study:** a researcher will ask you to complete a questionnaire about your health and wellbeing, and any further care you have received due to your injuries.
- We might contact you if we do not receive a questionnaire back from you. This will be via telephone or email, or by another preferred method where possible.
- We will also use information collected routinely by the Trauma Audit and Research Network (TARN). This data about people with injuries is routinely collected by hospitals in England and Wales to improve trauma care.
- **At 30 days and 6 months after you join the study:** we will also be asking a *few* study participants if they would be willing to talk to a researcher about their treatment and experience of taking part in this

study. This interview is optional and you do not have to take part; it won't affect your participation in the rest of the study.

- **At the end of the study:** we will be asking a *few* participants if they would like to help make a short film about the study and the experience of lung collapse - to make sure the results are understood by future patients. This is optional and you do not have to take part; it won't affect your participation in the rest of the study.
- Patient perspectives and experience are extremely important to this research and there are additional opportunities to get involved, for more information please get in touch using the contact details on the final page

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

Benefits. We cannot promise that the study will benefit you directly, however it will help us decide on the best ways to treat patients in future. We are unable to offer any payment or expenses for taking part in the study.

Disadvantages or risks. Even if you are treated without a chest drain in A&E, there is still a chance that you may need one later on. This may be needed as an emergency. The safety of all participants in the study will be closely monitored by an independent group of experts.

4. Will my GP be informed?

Yes. Your GP Practice will be informed in writing that you are taking part in this study. We do this so they know you're in the study, and so we can access medical records relevant to this study. With your permission, we may tell your doctor/GP if we have concerns about your health or well-being. If, however, there is a risk of harm to you or others, we *may* share such information without your consent.

5. What if I don't want to take part in the study anymore?

You can stop participating in the study at any time without giving a reason. Your medical care and legal rights will not be affected.

If you no longer want to complete questionnaires (or other optional elements of the study) that is OK. In this situation we will continue to collect relevant information from your medical notes, without bothering you, unless you tell us you don't want us to.

If you wish to stop participation completely, we will confidentially keep any information (data) collected about you up to the point of withdrawal to include in our analysis of the study results.

6. What happens if I lose capacity during the study?

In some cases, it is possible that due to an acute medical problem you may experience (temporary) mild to moderate confusion or loss of capacity during the study. If this happens:

We will seek advice from a Consultee about whether you should remain in the study. A Consultee is either a Personal Consultee (i.e. your partner, or a particular friend or unpaid carer), or if not available or willing to advise, a Nominated Consultee (a doctor unrelated (independent) to the study).

If your Consultee does not think it is suitable for you to remain in the study, then your participation in the study will stop. In this case, we will confidentially keep any information (data) collected about you up to that point to include in our analysis of the study results.

7. What if something goes wrong?

If you are unhappy about any aspect of this study, the doctor or nurse looking after you in the hospital 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 (NHS) complaints mechanisms will still be available to you.

8. 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 current data protection laws; Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR).

Relevant sections of your medical notes and relevant (electronic) records and information collected during the study may be looked at by authorised individuals from North Bristol NHS Trust (Sponsor) 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 of this information sheet explains in more detail about what will happen to your data if you take part in this study. Please continue over the page for more information.

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

1. How will we use information about you?

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

- Initials
- NHS number
- Name
- Sex and/or 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 provides the computer software that randomly decides which treatment group you are allocated to. Your local researcher will provide this company with the minimum relevant information about you to enable the randomisation process. They must follow our rules about keeping your information safe.

Some information (e.g. NHS number) may also be sent to the Trauma Audit and Research Network (TARN). TARN has agreements and procedures in place to ensure patient data are protected and processed correctly. 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 makes sure no-one will know that you took part in the study.

2. 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 the information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital and/or your GP without bothering you again. 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 may have the option to take part in future research using your data saved from this study.

3. 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: https://comited.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.e.williamson@nbt.nhs.uk
- By asking one of the research team: see last page
- By sending an email to: comited-trial@bristol.ac.uk, or by ringing us on 0117 394 0250

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

We aim to complete this research in late 2024 (may be subject to change). Once available, results will be published in medical journals and presented at conferences attended by healthcare professionals. Throughout the study, we plan to inform participants of study updates and results via newsletters. Updates and results will also be made accessible to participants and the wider public via our website, and potentially in a short film, for example. **You will not be personally identified in any report/publication.**

5. 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**.

6. 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.

7. 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 (NIHR132889). 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 Welsh Research Ethics Committee 4 (ref: 22/WA/0118) 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.

CoMiTED 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): see front page.

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