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

Invitation to become a Consultee

(Participant not regained capacity following Auto-enrolment)

We would like to invite you to become a Personal (or Nominated) Consultee regarding your relative/friend (the patient) who is unable to decide for themself whether they would like to continue to take part in a research study known as "CoMiTED". 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 any questions you may have. Thank you for taking time to read the supporting information.

Introduction

Your relative/friend (or the patient) recently attended the Accident and Emergency department (A&E) because of an injury. They were found to have a collapsed lung and, while they were in A&E, they were included in a research study called CoMiTED, "Conservative Management in Traumatic Pneumothoraces in the Emergency Department: A Randomised Controlled Trial".

The aim of CoMiTED is to find out which treatment is better for patients who have a collapsed lung (also known as a 'pneumothorax'). Doctors currently treat a collapsed lung by inserting a tube (chest drain) through the chest wall to help the lung re-inflate. We think that more patients could be safely treated without a chest drain, but there is currently no good research evidence one way or the other. We want to find out whether doctors should change their practice and treat fewer patients with a chest drain.

Normally a doctor or nurse will discuss a research study with a patient before anything happens to them. They will tell the patient what is involved, so they can decide whether or not to take part. If a patient is too unwell to be asked and needs emergency care, there is limited time to talk to the patient's relative/friend first about the research study before it begins. So, in these circumstances, doctors are allowed to include a patient in the research study. More information about this process can be found in a video on the CoMiTED study website: https://comited.blogs.bristol.ac.uk. When your relative/friend (the patient) arrived at this hospital, they were too unwell to be asked about taking part in this study so the doctors treating them agreed that it was safe and suitable for them to be included in this study, which is looking to improve care for patients. All research conducted within the NHS is approved by an independent ethics committee to ensure it is appropriate and ethical for patients to take part.

Now that it is possible, we would like to explain what the study is about, why we're doing it and what it means for your relative/friend (the patient). Further details about the study are provided in the separate participant information materials; Summary Participant Information Sheet (and/or equivalent video) and Detailed Participant Information Sheet; this is the same information which would have been provided to your relative/friend (the patient) upon arrival at the hospital if they had been well enough. If there is anything in the information supplied that you don't understand, please ask someone to explain it to you. The doctors and nurses involved will be happy to answer any questions you may have.

What is a Consultee?

We feel that your relative/friend (the patient) is still too unwell to decide for themself whether they would like to continue to take part in this study. An adult who is either temporarily or permanently unable to make a decision about their medical care for themselves is described as 'lacking capacity' under the Mental Capacity Act 2005. This law allows a Consultee to be appointed to give researchers advice as to the likely feelings and wishes of an adult who lacks capacity about taking part in a research study.

A Consultee can either be Personal or Nominated, but a person who lacks capacity can only have one Consultee at a time. We will always take reasonable steps to identify a Personal Consultee in the first instance.

- A **PERSONAL CONSULTEE** is someone who is unconnected to the research project. They personally know the person who lacks capacity and they are able to advise on the person's wishes or feelings. This could be the person's relative, friend, unpaid carer or a court appointee. They must not be someone who is paid to look after the person who lacks capacity.
- A **NOMINATED CONSULTEE** is also someone who is unconnected to the research project. However, this Consultee does not personally know the person who lacks capacity. They can ask other people close to the person who lacks capacity about the person's wishes or feelings. A Nominated Consultee may have a professional knowledge of the person who lacks capacity, such as their doctor or lawyer. They can be someone who is paid to look after the person who lacks capacity.

We would like to invite you to become a Consultee on behalf of your relative/friend (the patient) who lacks capacity so that you are able to give advice on their likely wishes regarding continuing taking part in the study. You must decide for yourself whether you want to take on the role, or not. If you are unsure about taking on the role of consultee, you may seek independent advice. We will understand if you do not want to take on this responsibility and you will not be asked to do anything further. Your relative/friend's medical care will *not* be affected if you tell us you do not want to take on the role of Consultee. If there are any parts of the information that you do not understand, you have any questions, or you would like further information, please ask.

What do I need to do as a Consultee?

A Consultee should think about why the research is being done, and what the practicalities, risks and benefits of taking part will be for the person who lacks capacity.

If you decide to take on the role of Consultee, please take your time to consider the study and your relative/friend's (the patient's) wishes and interests. Please let us know of any advance decisions they may have made about participating in research in the past if applicable; these should take precedence. After reviewing the separate participant information materials, a member of the research team will ask you to complete a Consultee Declaration Form that confirms your advice on whether your relative/friend (the patient) would wish to continue to take part if they had capacity to make that decision. You are not being asked to give consent, only advice. You will be given a copy of the completed Consultee Declaration Form for your records and your personal and research data will be kept for at least 5 years after the end of the study, held confidentially and securely by the research team.

What happens next?

If you advise that your relative/friend (the patient) would wish to continue to take part in the CoMiTED study, we would confidentially keep any information (data) we have already collected and continue to collect further relevant information. You could be asked to give your advice on other study-related issues for as long as the person remains a participant in the study. If you are acting as a Personal Consultee, you will also be asked if you would agree to being contacted by a researcher with a view to being interviewed about your relative/friend's experiences of taking part in the study and/or with a view to helping us to make a short film about the study and your relative/friend's experience of lung collapse. You do not have to agree to take part in either if you do not wish and this will not affect your relative/friend taking part in the rest of the study. If, as a Consultee, you come to believe at a later date that your relative/friend (the patient) would wish to stop taking part in this study, you should advise the clinical team that they should be withdrawn. Your advice will always be followed, they will be withdrawn and we will confidentially keep any information (data) collected up to that point to include in our analysis of the study results.

If you advise that your relative/friend (the patient) would *not* wish to continue to take part in the CoMiTED study, your relative/friend (the patient) will be withdrawn from the study and we will confidentially keep any information (data) collected up to that point to include in our analysis of the study results. Neither you nor your relative/friend

(the patient) will be contacted about the study again. If you do not wish for your relative/friend (the patient) to continue taking part, it will not affect the medical care they receive in any way. For us to understand why you have come to this decision, and to help in future research, you may be asked to answer a few questions, if you are willing.

If you wish to stop being a Consultee, you can do this at any time by informing the clinical team of the person who lacks capacity. Your relative/friend (the patient) cannot remain in the study without a Consultee, so they will be withdrawn the study if you stop being their Consultee and a new Consultee cannot be found.

What happens if my relative/friend (the patient) regains capacity during the study?

If your relative/friend's (the patient's) condition improves during the study and they become able to make their own decision about continuing to take part, a member of the research team will ask them whether they agree to continue to be a part of the study. Your relative/friend (the patient) will be provided with the separate participant information materials and it will be explained to them what has happened so far and what we are seeking their consent for. If your relative/friend (the patient) advises that they no longer wish to take part in the study, they will be withdrawn and we will ask if they give permission for us to confidentially keep any information (data) collected up to that point to include in our analysis of the study results.

You can find more details in the supporting Detailed Participant Information Sheet. If there are any parts of the information supplied that you do not understand, you have any questions, or you would like further information, please use the contact details on the Detailed Participant Information Sheet.

THANK YOU FOR READING THIS INFORMATION. PLEASE KEEP A COPY FOR YOUR RECORDS.

Sent on behalf of the CoMiTED Study Team

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