RASP

Radiological Assessment of Pneumothorax

Patient Information Sheet

You are being invited to take part in a study called "RASP". Before you decide whether to be involved, it is important for you to understand why we are conducting this study and what it will mean for you. Please feel free to discuss this information with someone else, such as your family or GP, if you wish. Please ask any questions if you feel there is something which is not clear, or if you would like to know more.

Summary:

This study is designed to assess whether we can use a CT scan to identify the site of an air leak in patients with a collapsed lung (**pneumothorax**) and whether having a tube in to remove the air (an **intercostal chest drain**) makes the leak of air from the lung worse.

Information from this study may serve as a basis for larger research studies in the future, which could change the way that we manage patients with a collapsed lung; being able to identify where the air is leaking from opens the door for future research into providing targeted treatments to seal the leak, and knowing whether tube drainage is worsening or prolonging the leak of air may reassure us that we can take patients' tubes out earlier without risking the lung collapsing again.

Contact details:

Your principal investigator is:	Dr Steven Walker
For routine trial-related questions during working hours, please contact:	0117 414 8114
For emergency or non-trial-related issues please contact medical services as usual	

Part A – What's involved?

1. What is the purpose of the study?

A collapsed lung or **pneumothorax** is a collection of air around the outside of the lung, in the space between the lung and the chest wall – the **pleural space**. This is usually due to a leak of air from the lung itself, which may occur as a result of an injury or a procedure performed by a healthcare professional, or it can happen spontaneously, without any clear cause.

It is sometimes necessary for us to remove the air from around the outside of the lung by inserting a **chest drain.** This is a temporary plastic tube inserted between the ribs to allow the air to escape into a bottle filled with water or a digital device, to allow the lung to re-inflate. (Fig 1)

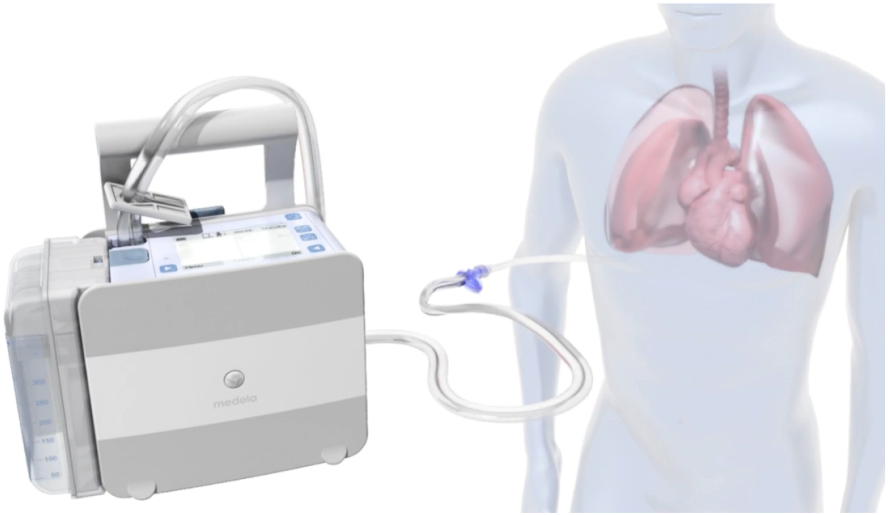
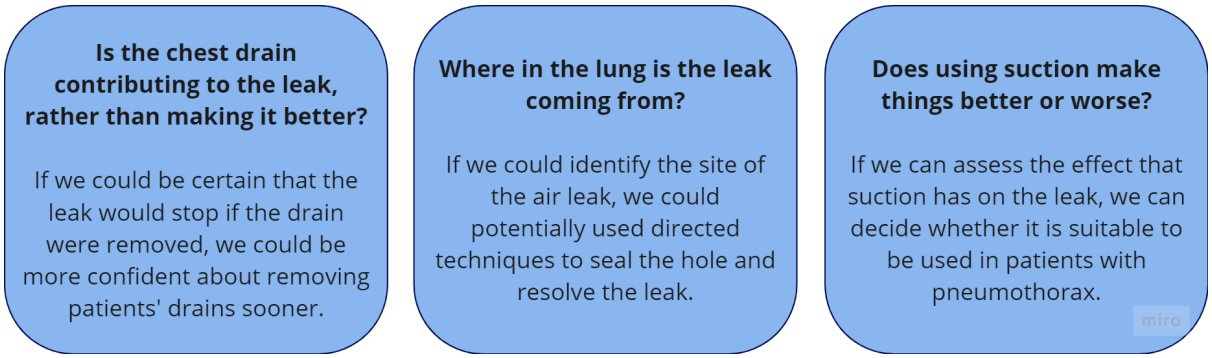


Fig 1. A chest drain connected to a digital device to monitor the air leak (Medela Thopaz)

In some patients, air continues to leak out from the lung into the pleural space and out through the drain. We call this a **persistent air leak.** Some doctors believe that having a chest drain in may contribute to the development of persistent air leak by creating a difference in pressure between the lung, the pleural space and the drain. Sometimes we use an electronic device to suck air out through the chest drain more rapidly (**suction**), but some doctors believe that this could make the pressure difference bigger and hold open the hole through which air is escaping.

If a patient develops a persistent air leak, there are several uncertainties:



This study aims to evaluate the ability of a special type of CT scan to identify the site of a leak in patients with a pneumothorax. We will be investigating:

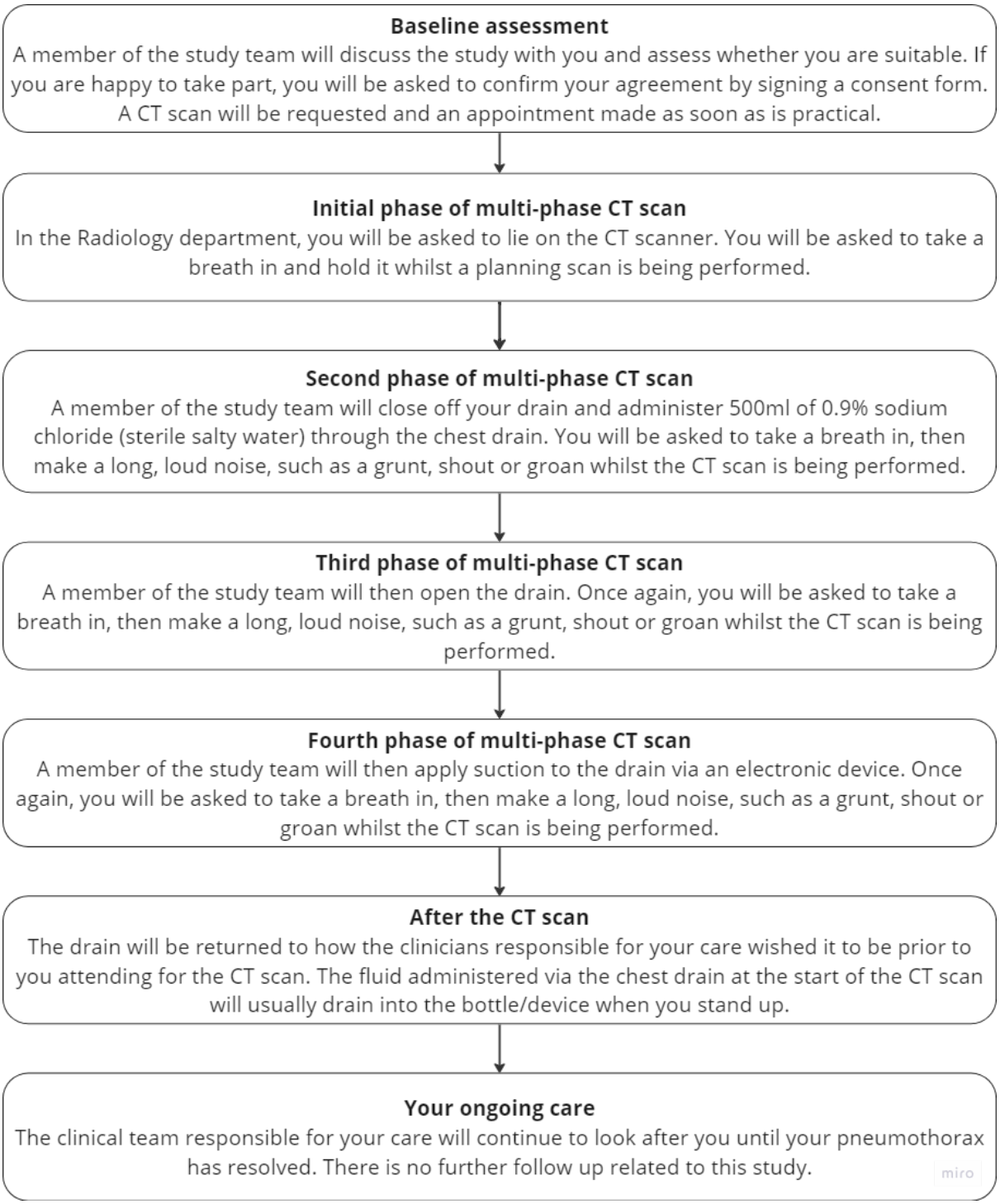
1) Whether the scan can identify a leak of air from the lung into the pleural space.
2) Whether the scan can pinpoint the site of the air leak.
3) Whether the scan can assess the size of the leak of air, and how this compares to a digital measurement of the leak.
4) Whether the air leak stops when the drain is clamped.
5) What effect putting the drain has on suction on the size of the air leak.

This study is being conducted as part of a PhD project under the supervision of Dr Steve Walker.

2. Why have I been invited?

You have been chosen because you have a pneumothorax (collapsed lung), for which the doctors have needed to insert a chest drain. From looking at the bottle or device connected to your drain, the doctors can tell that you have an ongoing leak of air from the lung into the pleural space.

3. What will happen to me during the study?



In total, the CT scan will take about 15 minutes to complete; much of this will be preparation for the scan, with each phase of the scan lasting just a few seconds.

4. Will I find out the results of the scan?

The clinical team responsible for your care will be able to inform you of the results of your CT scan, once the scan has been reported. If we find something unexpected that is clinically relevant (an **incidental finding**) we will let your clinical team know.

5. What will be measured?

After the CT scan, the images will be processed and reconstructed. They will then be reviewed by two independent radiologists who will evaluate for each scan:

- Whether there is an identifiable leak point
- Where that leak point is
- The size of the leak point.

They won't know whether the drain is open, closed or on suction at the time of the scan.

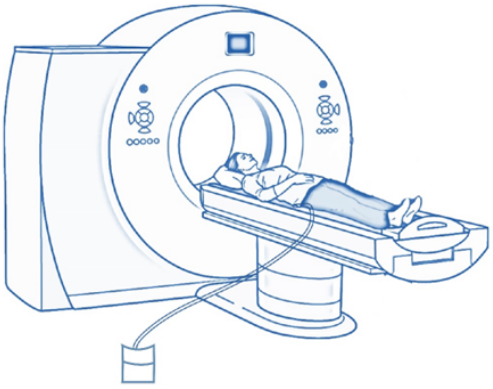


Fig 2. Patient with a chest drain having a CT

We will also record the size of the air leak on the digital device attached to your drain during each of the phases of the CT scan.

6. What happens when the study has finished?

Once you have had your CT scan, you will go back to the ward. The clinical team responsible for your care will continue to look after you until your pneumothorax is resolved. There is no further study follow up.

7. Do I have to take part?

No, you can decide whether to take part in the study or not. If you decide not to take part, you do not have to explain why. Your decision will not affect the medical care that you receive or your legal rights in any way.

8. What are the potential disadvantages of taking part?

Risks/disadvantages associated with administering fluid via the chest drain:

During the study, we will administer 500ml of 0.9% sodium chloride **(saline)** solution into the chest drain. Saline is commonly used in patients with chest drains; we will often flush a chest drain several times a day to ensure that it doesn't become blocked or use larger volumes of saline to break down pockets of fluid in patients with infection in their pleural space.

The saline itself is very safe but sometimes can be a little uncomfortable as it is administered and can sometimes leak out from around the drain as well as through it. There is a very small risk that we can introduce infection into the space when we access the drain to administer the saline, but we wash our hands, wear sterile gloves and clean the tap attached to the drain thoroughly to reduce that risk.

Risks/disadvantages associated with clamping the drain:

On occasion, air can accumulate again in the pleural space when the drain is closed off, if the air leak continues. A member of the study team will be present during your CT scan and will be monitoring you closely. If you feel more breathless or develop worsening chest pain during the CT scan, let the radiographer know and we will open the drain again. This will allow any air that has accumulated to drain out and resolve your symptoms quickly.

Risks/disadvantages associated with CT scans:

CT scans are often used to investigate patients with a pneumothorax, either to ensure that the drain is adequately positioned within the chest or to look at the underlying lung tissue to explore why you may have developed a pneumothorax in the first place.

If you take part in this study, you will have a multi-phase CT scan of the chest. This will be extra to that which you would have if you did not take part in the trial. This procedure uses ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will increase the chances of this happening to you to about 50.11 % (0.11% increase over natural incidence).

9. What are the potential advantages of taking part?

Your participation in this study will help improve our understanding of air leak in patients with pneumothorax and evaluate how good this CT scanning technique is at demonstrating an air leak. With this information, we will be able to run larger studies, with the results of which we may be able to offer more targeted therapies to treat air leak and resolve a patient's pneumothorax more quickly. This could benefit patients in your position in the future.

10. Will I be contacted about the study again in the future?

No. Once you have had your CT scan, there is no further involvement in the study. Your care will continue under the team responsible for you and you will not be contacted in the future.

11. Can I change my mind and withdraw from the study once I've joined?

You can change your mind and withdraw from the study at any point. You can withdraw your data at any time until the database is locked at the end of the study. You do not need to explain why, and your medical care and legal rights will not be affected in any way. If you wish to withdraw, please contact your local trial team using the contact details on the front of this information sheet.

PART B – Further supporting information

1. How will we use information about you?

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

- initials
- NHS number
- name
- medical history.

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.

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. Your data will be archived for 5 years as per North Bristol standard operating procedures.

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 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. 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.

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, available at www.nbt.nhs.uk/patientresearchdata
- by asking one of the research team
- by contacting Helen Williamson (Head of Information Governance) at helen.e.williamson@nbt.nhs.uk or by ringing **0117 414 4767**
- by ringing the Respiratory Research team on **0117 414 8114** (Mon-Fri 8-4)

4. Who is organising and funding the study?

The study is sponsored by the North Bristol NHS Trust and it is being conducted by the University of Bristol's Academic Respiratory Unit. The study is funded by the Academy of Medical Sciences. The funder will not have access to your data.

5. Stopping the trial

If the study doctors feel that it is no longer safe or appropriate for you to continue in the trial, they may want to withdraw you from the study. Very occasionally, the sponsor (North Bristol NHS Trust) may also stop the study early. If this happens, the reasons will be explained to you.

6. Who has reviewed the study?

This study has been designed by experts in pleural disease from Bristol and elsewhere. The study has been approved by an NHS Research Ethics Committee.

7. What if there is a problem?

If you have a concern or are displeased about any aspect of this study or your wider care, then we would encourage you to ask to speak to a study doctor or nurse who will attempt to address any issues you may have. If you remain unhappy and wish to make a formal complaint, then you can do this through the NHS complaints procedure. We can provide you with information on how to contact either the Patient Advice and Liaison Service (PALS) or the hospital complaints manager. These details can also be obtained through the hospital switchboard.

PALS can be contacted on pals@nbt.nhs.uk or 0117 414 4569.

To raise a concern or complaint, please email complaints@nbt.nhs.uk or call 0117 414 4567

This study is covered by the NHS Indemnity Scheme.

8. Will I find out the results of this research?

This study is designed to run for 24 months, and results will be published following completion of the study. A summary of the results will be made available to participants, if they wish.

The results of this research will be published in scientific journals and presented at conferences. If you wish to find out the results of this study, once published, they can be found on the Academic Respiratory Unit website at www.bristol.ac.uk/translational-health-sciences/research/respiratory/

Thank you for taking the time to read this information, and for considering taking part in the RASP study.