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Advanced CT examination of collapsed lungs: looking for the leak point

Submission date
13/11/2024

Recruitment status
Recruiting

Registration date
30/12/2024

Overall study status
Ongoing

Last Edited
30/12/2024

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Potential participants will be identified from patients presenting with a traumatic, iatrogenic or spontaneous pneumothorax to North Bristol NHS Trust by a clinician working within the trust.

What does the study involve?
A member of the study team will discuss the study with you and assess whether you are suitable. If you are happy to take part, a CT will be requested for you as soon as is practical. In the radiological department, you will be asked to lie down in the CT scanner. A member of the study team will close of your chest drain and administer sterile water solution through your drain. You will be asked to make a long loud noise. The will be four phases of CT scans. There is no follow-up requirements with the study.

What are the possible benefits and risks of participating?
Benefits:
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.
Risks:
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.

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.

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).

Where is the study run from?
North Bristol NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2024 to May 2026

Who is funding the study?
Academy of Medical Sciences (UK)

Who is the main contact?
Dr Steve Walker, steven.walker@bristol.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327232

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61757, SGL027\1076

Study information

Scientific Title
Radiological ASsessment of Pneumothorax (RASP)

Acronym
RASP

Study objectives
Primary objective:
To assess the utility of 320-MDCT in identifying visceral air leak in patients with spontaneous, traumatic or iatrogenic pneumothorax

Secondary objectives:
1. To test whether open continuous drainage increases incidence of visceral pleural leak point when compared to closed (clamped) drainage.
2. To evaluate the relationship between digital air leak (DAL) measurements and detectable

visceral pleural leak point identified on 320-MDCT.
3. To determine whether application of digital suction increases the incidence of visceral pleural leak point when compared to no suction.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/04/2024, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8063; cambridgecentral.rec@hra.nhs.uk), ref: 24/EE/0072

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Pneumothorax

Interventions
A multi-phase 320-MDCT scan will be requested and performed at the earliest convenience. Whilst the participant is on the CT trolley, digital assessment of the air leak and an ultra-low dose helical whole chest CT scan will be performed. 500ml of sterile 0.9% sodium chloride will then be instilled into their chest drain and the drain clamped. The next phase of the CT scan will then be performed whilst the participant makes a sustained loud vocalisation (such as a moan or yell). The drain will then be unclamped and the next phase of the CT scan performed whilst the participant makes a sustained loud vocalisation (such as a moan or yell). The drain will then be placed on -20cm of suction and the final phase of the CT scan performed whilst the participant makes a sustained loud vocalisation (such as a moan or yell).

Once the scan is complete, the drain will be left unclamped and suction returned to pre-intervention settings as decided by the clinician responsible for their care. The participant will return to the ward and their ongoing care will continue under their clinical team. There is no further trial follow up required.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of identification of visceral air leak on 320-MDCT by radiologist

Secondary outcome measures
1. The proportion of participants in whom a visceral air leak is identified on 320-MDCT with the drain clamped, unclamped and on suction
2. Measurement of digital air leak on a Thopaz device with the drain unclamped and on suction

Overall study start date
16/04/2024

Completion date
12/05/2026

Eligibility

Key inclusion criteria
1. Spontaneous, traumatic or iatrogenic pneumothorax
2. Chest drain in situ for management of pneumothorax
3. Detectable ongoing air leak

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Key exclusion criteria
1. Unable to lie flat
2. Unable to tolerate clamped ICD
3. Aged less than 50 years of age
4. Pregnant or breastfeeding patient
5. Inability to consent or comply with trial requirements.

Date of first enrolment
30/11/2024

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital, Southmead Road, Westbury-on-Trym
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BS10 5NB
+44 71174149330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Research organisation

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be reported via a high-impact medical journal and present findings at international medical, respiratory and emergency medicine conferences.

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	05/04/2024	19/12/2024	No	Yes