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CoMiTED: investigating whether a collapsed lung (pneumothorax) due to injury (trauma) can be safely and effectively treated without immediately inserting a tube into the chest (chest drain)

Submission date
27/06/2022

Recruitment status
No longer recruiting

Registration date
04/07/2022

Overall study status
Completed

Last Edited
13/05/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Patients aged 16 years or older who have been admitted to the Accident and Emergency department (A&E), with a collapsed lung due to injury.

What does the study involve?
Participants, when they join the study, will be put into one of two groups. One group will have treatment with a chest drain (current usual care) and the other group will be treated without a chest drain to start with. Participants will be allocated randomly (like tossing a coin) and have an equal chance of receiving either treatment. All participants will be assessed and monitored according to the usual care of the hospital.

Participants will complete questionnaires at 30 days, 3, and 6 months and the study team will review their medical notes.

What are the possible benefits and risks of participating?
In general, the trial will not expose participants to risks additional to routine care. The trial will, however, expose trauma victims to the potential downsides of the established pathways used in clinical practice: those allocated to usual care may have a chest drain inserted without the opportunity for conservative management (and potentially unnecessarily), while a proportion of those allocated to conservative management may be perceived as suffering a delay to the insertion of chest drain that becomes necessary at a later stage in their care. This is supported by PPI. Study procedures will include questionnaires at each time point. This will use the participant's time, but no other inconvenience or risk is expected. The questionnaires have been reviewed by our PPI team to ensure they are acceptable to patients.

By taking part in this study, participants will help to demonstrate whether conservative management is effective and cost-effective in the initial management of traumatic pneumothoraces. This may help and influence the treatment of patients in the future.

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?
From October 2021 to March 2025

Who is funding the study?
National Institute for Health and Care Research (UK)

Who is the main contact?
Miss Nikki Blythe, nikki.blythe@bristol.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
312833

Central Portfolio Management System (CPMS)
52683

National Institute for Health and Care Research (NIHR)
132889

Protocol serial number
Grant Codes:

Study information

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

Acronym
CoMiTED

Study objectives
The aim of this study is to establish whether initial conservative management of significant traumatic pneumothoraces is non-inferior to invasive management in terms of subsequent emergency pleural interventions, complications, pain, breathlessness, and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2022, Wales REC 4 (Health and Care Research Wales Support Centre, Castlebridge 4 , CF11 9AB; +44 (0)7976 982591; Wales.REC4@wales.nhs.uk), ref: 22/WA/0118

Primary study design
Interventional

Study design
Multicentre parallel-group individually randomized controlled non-inferiority trial with an internal pilot, an economic evaluation, and an integrated qualitative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traumatic pneumothorax

Interventions
Participants will be allocated in a 1:1 ratio to either “initial conservative management (intervention group)” or “chest drain insertion in the ED (control group)”.

Randomisation will be carried out using an online system and the randomisation sequence will be generated by the company called “Sealed EnvelopeTM”. Appropriate staff at all sites, as delegated by the PI, will be provided with log-in details for the secure online randomisation system, and study database where applicable.

In the intervention (initial conservative management) group, the treating clinician will be advised to manage the participant without chest drain insertion and undertake observation and admission to a hospital ward or ICU.

In the control group (chest drain insertion in the ED), it is assumed that all patients will have a chest drain inserted. It is standard practice for chest drains to be inserted immediately after an imaging diagnosis in the ED.

Internal pilot:
Following set-up, we will carry out an internal pilot for up to six months, at approximately five sites. In this pilot, we aim to confirm the feasibility of the trial processes including, recruitment of participants, randomisation, and adherence to the allocated intervention arm. Detailed information will be gathered during the internal pilot from both the qualitative and quantitative elements of the study to inform optimisation and refinement of study processes. Completeness of TARN data and number of randomised trial patients who are eligible for TARN inclusion will be established during the internal pilot to streamline data collection for the main trial. The pilot will be evaluated using quantitative progression criteria and a qualitative exploration of the acceptability of the trial. Participants recruited to the internal pilot will be included in the final analysis.

On progressing to the main trial recruitment period, we will immediately extend recruitment to approximately 20 additional sites for a further 12 months recruitment.

Baseline questionnaire:
''Baseline'' data collection will take place after initial enrolment (randomisation) in the ED has taken place. Participants will be asked to complete the questionnaire according to how they feel at the time of completion, rather than retrospectively.

Follow up:
Participants will be contacted at 30 days (+10 days) following randomisation, 3 months, and 6 months (-/+ 10 days) to complete a follow-up study questionnaire, which will include questions about their pain and function, breathlessness, quality of life and wellbeing.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Need for one or more subsequent emergency pleural interventions (excluding chest drain insertion in the ED) measured using patient records/electronic patient tracking systems up to 30 days

Key secondary outcome(s)
The following will be measured at specified timepoints post-randomisation:
1. All pleural interventions (including chest drain insertion in the ED) measured using patient records/electronic patient tracking systems up to 30 days
2. All complications of pleural intervention measured using patient records/electronic patient tracking systems up to 30 days
3. Total days of pleural drainage measured using patient records/electronic patient tracking systems up to 30 days
4. Patient-reported pain, function, and breathlessness measured using validated Brief Pain Inventory and MRC dyspnoea scale (Patient Reported Outcome Measures) at baseline, 30 days, 3 and 6 months
5. Quality of life measured using EQ-5D-5L questionnaire and Impact of Events Scale-Revised at 30 days, 3 and 6 months
6. Total length of stay (hospital and Intensive Care Unit (ICU), including readmission) measured

using patient records/electronic patient tracking systems up to 30 days
7. Adjudicated mortality (pneumothorax or chest injury related) measured using patient records /electronic patient tracking systems at 30 days
8. All-cause mortality measured using patient records/electronic patient tracking systems at 6 months
9. Cost per quality-adjusted life year (QALY) measured using the data collected in secondary outcomes "1., 2., 4., 5., 6., 7., and 8." supplemented by a study-specific patient resource use questionnaire at 6 months
10. Patient/consultee views and experiences of conservative management/chest drain measured using qualitative interviews at 30 days and 6 months
11. Clinician views of conservative management/chest drain measured using qualitative interviews throughout the trial

Completion date
02/03/2025

Eligibility

Key inclusion criteria
1. Presenting to the Emergency Department with traumatic pneumothoraces
2. Aged, or believed to be aged, ≥16 years
3. The treating clinician(s) are uncertain if a chest drain is required

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Total final enrolment
400

Key exclusion criteria
1. Treating clinician(s) believe injuries are incompatible with life
2. Respiratory arrest
3. Haemothorax requiring a chest drain in the opinion of the treating clinician(s)
4. Clinical and imaging evidence of tension pneumothorax
5. Prisoners (does not include those in police custody; only those detained in prison establishments)
6. Retrospective paediatric exclusion if patient confirmed to be aged <16 years

Date of first enrolment
08/08/2022

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Manchester University NHS Foundation Trust
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Torbay And South Devon NHS Foundation Trust
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre

Macclesfield District General Hospital
Macclesfield District Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
The Grange University Hospital
Caerleon Road
Cwmbran
United Kingdom
NP44 8YN

Study participating centre
Royal United Hospital
Combe Park
Bath
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BA1 3NG

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre

University Hospital (coventry)
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
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TN2 4QJ

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury St Edmunds
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IP33 2QZ

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CF14 4XW

Study participating centre
Gloucestershire Royal Hospital
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GL1 3NN

Study participating centre
Bristol Royal Infirmary
Marlborough Street
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BS2 8HW

Study participating centre
Broomfield Hospital
Court Road
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Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Watford General Hospital
60 Vicarage Road
Watford
United Kingdom
WD18 0HB

Study participating centre
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
University College London
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
The Royal Victoria Hospital
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Study participating centre
Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
The Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Prince Charles Hospital
Merthyr/cynon Unit
Merthyr Tydfil

United Kingdom
CF47 9DT

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Royal Liverpool University Hospital
Royal Liverpool University Hospital NHS Trust
Prescot Street
Liverpool
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L7 8XP

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The dataset will be published in the publicly available University of Bristol Research Data repository (https://www.bristol.ac.uk/staff/researchers/data/accessing-research-data/).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/06/2024	19/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	07/07/2022	19/07/2022	No	No
Protocol file	version 6.0	23/02/2024	29/04/2024	No	No
Protocol file	version 7.0	23/07/2024	08/10/2024	No	No
Statistical Analysis Plan	version 1.0	12/05/2025	13/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes