

# 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)

<b>Submission date</b> 27/06/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/07/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/05/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:nikki.blythe@bristol.ac.uk)

### **Study website**

<https://comited.blogs.bristol.ac.uk/>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Edward Carlton

### **ORCID ID**

<http://orcid.org/0000-0002-2064-4618>

### **Contact details**

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United Kingdom

BS10 5NB  
+44 (0)7595 040112  
Ed.Carlton@nbt.nhs.uk

**Type(s)**

Public

**Contact name**

Miss Nikki Blythe

**Contact details**

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**Type(s)**

Scientific

**Contact name**

Prof Edward Carlton

**ORCID ID**

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Ed.Carlton@nbt.nhs.uk

**Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

312833

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 312833, CPMS 52683, Grant Codes: NIHR132889

## **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

**Study design**

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

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Available at <https://comited.blogs.bristol.ac.uk/>

**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 Envelope™”. 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 measure**

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

### **Secondary outcome measures**

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

**Overall study start date**

01/10/2021

**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,  $\geq 16$  years
3. The treating clinician(s) are uncertain if a chest drain is required

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 400; UK Sample Size: 400

**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**

England

Northern Ireland

Scotland

United Kingdom

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  
United Kingdom  
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  
Tunbridge Wells  
United Kingdom  
TN2 4QJ

**Study participating centre**

**West Suffolk Hospital**

Hardwick Lane  
Bury St Edmunds  
United Kingdom  
IP33 2QZ

**Study participating centre**

**University Hospital of Wales**

Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**

**Gloucestershire Royal Hospital**

Great Western Road  
Gloucester  
United Kingdom  
GL1 3NN

**Study participating centre**

**Bristol Royal Infirmary**

Marlborough Street  
Bristol  
United Kingdom  
BS2 8HW

**Study participating centre**

**Broomfield Hospital**

Court Road  
Broomfield  
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  
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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  
United Kingdom  
L7 8XP

## **Sponsor information**

**Organisation**  
North Bristol NHS Trust

**Sponsor details**  
Research and Innovation  
North Bristol NHS Trust Floor 3  
Learning & Research Building  
Southmead Hospital  
Westbury-on-Trym

Bristol  
England  
United Kingdom  
BS10 5NB  
+44 (0)1174149330  
researchsponsor@nbt.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nbt.nhs.uk/>

**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, HTA

**Funding Body Type**

Government organisation



**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Publication and dissemination plan**

The aim will be to publish our primary manuscript in a high impact medical journal, and present our findings at multiple conferences. We will communicate our findings to the British Thoracic Society, NICE, and NHS England to incorporate our work into relevant national guidelines and develop a film about the project with the help of involved patients and our patient advisors to ensure our findings reach diverse audiences. We will also complete a full report for the NIHR.

**Intention to publish date**  
31/12/2025

**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?
<a href="#">Protocol file</a>	version 3.0	07/07/2022	19/07/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 6.0	23/02/2024	29/04/2024	No	No
<a href="#">Protocol article</a>			17/06/2024	Yes	No
<a href="#">Protocol file</a>	version 7.0	23/07/2024	08/10/2024	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	12/05/2025	13/05/2025	No	No