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Comparing large chest drains with small chest drains to explore the best treatments for chest injury

Submission date
30/01/2026

Recruitment status
Recruiting

Registration date
17/02/2026

Overall study status
Ongoing

Last Edited
07/05/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] 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
Injuries to the chest can cause air or blood to collect in the space between the lungs and the ribs. Doctors usually put a tube in to drain it, but they're not sure if using a smaller tube or a bigger one is better. This research compares two treatments: one uses a small tube put in the chest with a needle and wire (called a small-bore Seldinger chest drain), and the other uses a large tube put in by cutting a hole in the chest (called a large-bore surgical chest drain).

Doctors have treated these lung problems for many years using large-bore surgical chest drains to re-inflate the lung or drain the blood. Every year, over 30,000 injured patients in the UK get this treatment in hospital. Although used across the NHS, large chest drains can cause serious problems like infection, bleeding, pain and scarring. Recent research shows that small chest drains put into the chest using a needle and wire could be a safer treatment option. Small chest drains are already used for other medical issues, but doctors are unsure about their use for treating injuries. The study finds out if these small chest drains are safer and more effective than larger ones. It also wants to know if they could cut down the NHS treatment costs.

This study will help to show if treating a collapsed lung or bleeding around the lung after injury with a small chest drain is better for patients. It will help the NHS choose the best treatment for patients needing a chest drain after injury, and it is an important research question for doctors and patients. The results will be written in journals, read by doctors, spoken about at conferences and shared with participants. The team plans to make a short film about the study results by working with patient groups. It includes storytelling to bring the topic to life for doctors and patients. The team will work with important NHS organisations so that the results change practice quickly.

Who can participate?
Patients presenting in the accident and emergency (A&E) department with a collapsed lung or bleeding after injury and in need of a chest drain are asked to take part in the study. Some patients might be too unwell to agree to join the study, so the team seeks advice from a consultee or personal legal representative, either before including them or later on.

What does the study involve?
The study involves around 1600 adult patients from around 50 hospitals in the UK. The team has developed networks, an understanding of local governance and knowledge of local populations. They have approached large centres that have agreed to participate in this study. In addition, they have designed the consent process to allow the inclusion of a large number of Scottish sites.

As each participant joins the study, a random process is used to determine whether they go into the group receiving the small drain or the group receiving the large drain. Everyone gets the same care, apart from the type of drain that is used. The team studies both groups and compares them. They see how good each treatment is and if serious health problems happen over the next 30 days. Participants are asked about their general health, wellbeing and if they have had any issues with breathing or pain at 30 days and six months. The team compares the two treatment groups to see which one works best for patients and makes better use of NHS resources. They interview some clinicians who are working on the study early on, to get their advice on how they can involve as many patients as possible in the time available and organise plans to support study teams.

They have already worked with people from groups who are most likely to be involved in the study – older people who have fallen, people who suffer injuries from major accidents, and victims of knife crimes – to help design the research. They keep working with these groups to ensure the research gets the best results for patients and is easy for everyone to understand.
The study involves the following procedures:

A member of the clinical team and/or research nurse provides the patient with study information. Approach can be made in A&E, theatre, ICU or on a ward, up to 24 hours after presentation.
A member of the clinical team and/or research nurse, appropriately trained and delegated, receives consent from the patient, their consultee or personal legal representative. Consent may be received in A&E, theatre, ICU or on a ward.
Patients, consultees and legal representatives can optionally provide verbal consent to the audio recording of the consent discussion. The member of the clinical team and/or research nurse discusses this optional element. Recording could take place in A&E, theatre, ICU or on a ward.
The recruiting doctor or appropriate research staff performs randomisation using the secure online randomisation system.
A research nurse, or other delegated site staff member, completes baseline data collection. Data is collected from hospital medical notes and GP records.
Participants are asked to complete a booklet of questionnaires at baseline, 30 days post randomisation and 6 months post randomisation. The baseline questionnaires are completed in person, up to 7 days post randomisation. This can be completed with the assistance of a researcher, member of the clinical team or person with caring responsibilities. Follow-up questionnaires (30 days and 6 months) are offered in a range of formats, as per participant preference, to include paper, online and telephone. The questionnaires can be completed with assistance or by a consultee/personal legal representative.

Intervention procedures:
Clinicians insert the large chest drain in A&E/theatre/ICU/on a ward.
Clinicians insert the small chest drain in A&E/theatre/ICU/on a ward.

What are the possible benefits and risks of participating?
The potential benefits for participants are summarised in the Participant Information Sheet (PIS), which has been reviewed and contributed to by public contributors.

It is unknown whether participation directly benefits participants. The main benefit is to inform future care of patients who are injured and require treatment of their chest injuries. It will be known if small drains can be used safely in this patient population.

As this is a trial evaluating a smaller drain size and a different insertion technique, there may be risks from participating. Smaller drains are already used safely across the NHS; however, this trial uses them in a different population (injured patients). As such, participant safety is closely monitored. Complications related to chest drains are the primary outcome measure. The additional burden related to follow-up is minimised. Participants are not required to attend the hospital and are offered a range of formats to complete questionnaires (post, online, telephone).

Where is the study run from?
Bristol Trials Centre, Population Health Science, University of Bristol, UK.

When is the study starting and how long is it expected to run for?
May 2026 to March 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA), UK.

Who is the main contact?
Graziella Mazza (Trial Manager) – comited2-trial@bristol.ac.uk

Contact information

Type(s)
Public

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Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
348038

Central Portfolio Management System (CPMS)
64545

National Institute for Health and Care Research (NIHR)
168228

Study information

Scientific Title
Randomised trial of the clinical and cost effectiveness of small bore, Seldinger, versus large bore, surgical, chest drains for the treatment of traumatic haemo/pneumothoraces – (CoMiT-ED 2)

Acronym
CoMiT-ED 2

Study objectives
This study aims to establish whether small-bore Seldinger chest drains are superior to large-bore surgical chest drains in terms of major complication rates in adult patients presenting to the hospital with traumatic chest injury (haemopneumothorax) requiring a chest drain.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 27/01/2026, Wales Research Ethics Committee 4: IRAS 348038 (Health and Care Research Wales , Floor 4, Crown Building Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC4@wales.nhs.uk), ref: 25/WA/0362

2. submitted 16/02/2026, Scotland A Research Ethics Committee: IRAS 364504 (-, -, -, United Kingdom; -; loth.sesres@nhs.scot), ref: -

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Trauma and Emergency Care, Primary sub-specialty: Emergency Medicine; Health Category: Injuries and accidents, Respiratory; Disease/Condition: Injuries to the thorax

Interventions
Trial design and setting
This is a pragmatic multicentre, parallel-group, individually randomised, superiority trial with internal pilot, economic evaluation and integrated QRI.

The trial will recruit patients from approximately 50 Major Trauma Centres and Trauma Units across the UK (potentially subject to change and dependent on recruitment rates).

Internal pilot:
We plan to test trial processes and feasibility using staged enrolment of sites over a 12-month feasibility window, from the time the first participant is recruited. Each site will aim to recruit 2 participants per month.

Planned recruitment:
On progressing to the main trial period, we will immediately extend recruitment to an additional 35 sites (with staggered opening of 3 sites/month) over a further 21 months.

Quintet Recruitment Intervention (QRI): We recognise challenges to trial recruitment in emergency settings, such as out-of-hours patient presentation, multiple inpatient specialities involved in decision making and inherently busy and time-pressured environments. We have planned to address these challenges by integrating the QRI during the internal pilot. The QRI is a mixed-methods intervention developed to optimise recruitment and consent. It involves intensive investigation to understand recruitment challenges and provide training and support to recruiters. It has strong evidence of effectiveness in complex RCTs and comprises two iterative and overlapping phases:

Phase 1 - Understanding recruitment: We will investigate factors influencing recruitment (e.g. patient recruitment pathways, eligibility criteria, equipoise issues and other barriers to recruitment and retention) and train recruiters during study setup, combining evidence from previous QRIs and training programmes with data collected from professionals involved in the previous CoMiT-ED trial. Once recruitment starts, we will use a multi-faceted and flexible approach, using triangulation of data, to understand recruitment as it happens.

Phase 2 - Development and implementation of recruitment strategies: Phase 1 findings will be reported iteratively to the Chief Investigators (Cls) and the TMG to inform plans to address identified barriers to recruitment, such as modifying discussions with site teams and how training is delivered to new and multiprofessional recruiters.

Phases 1 and 2 will be undertaken iteratively and cyclically, continuing throughout the first 12 months of recruitment with close monitoring of changes in screening log data and recruiter practice. The QRI research team will work closely with the CI/TMG, clinicians and the PPI advisory group members to deliver recruitment strategies that are sensitive and appropriate to the target study population to optimise recruitment and informed consent.

Blinding:
Only researchers evaluating outcomes for the analyses can be blinded to treatment group allocation, except where otherwise specified. Two statisticians based at the University of Bristol (UOB) will support this trial. The senior (lead) statistician will be blinded throughout the trial. The second trial statistician will be unblinded and will perform all disaggregated analyses according to a pre-specified Statistical Analysis Plan (SAP) and will attend closed DMEC meetings as required. In addition, the health economist(s) (UoB/Warwick) will be blinded when cleaning data and preparing the analysis plan, but unblinded when conducting the analysis.

Identification of participants:
Recruitment will be undertaken 24 hours a day, 7 days a week by trained clinical staff or research staff. Recruitment out of normal research staff hours will be facilitated through targeted training of emergency clinicians and wider professional groups (such as radiographers) at participating sites, supported by members of the Trainee Emergency Medicine Research Network (TERN), the Incubator for Diagnostic and Therapeutic Radiographers and the NIHR Associate Principal Investigator (API) Scheme.

Patients will present to the hospital through multiple routes and, where a traumatic haemo /pneumothorax is suspected, initial imaging (CT scan) will usually be performed within the first hour of their attendance. Imaging to identify traumatic haemo/pneumothoraces will be undertaken at the discretion of local clinical teams and will, in almost all cases of suspected traumatic haemo/pneumothoraces, include CT according to national guidance. This forms part of routine care and will not be altered for trial purposes.

Potentially eligible participants will be identified after a confirmed diagnosis of traumatic haemo /pneumothorax, on CT, by clinical staff or research nurses. Full eligibility must be assigned by an appropriately trained clinician (e.g. a doctor, nurse, physiotherapist and/or radiographer).

Potential participants transferred from non-recruiting sites can be approached for recruitment. If a participant is recruited at a recruiting site and later transferred elsewhere, their participation in the trial will be ongoing, and the initial recruiting site will remain responsible for follow-up.

This CRF will be developed in line with the SEAR (Screened, Eligible, Approached, Randomised) framework, which will enable us to record the flow of potential participants through the recruitment process, in line with recommended Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines, and monitor equipoise for the trial duration. Each potential participant screened will be allocated a unique screening number. Participants who go on to be randomised will additionally be allocated a unique study identification (I.D) number. Where possible, the screening CRF will include reason(s) for non-participation.

Given the setting of this trial (i.e. the ED, 24 hours a day, 7 days a week), it is acknowledged that completion of a screening CRF may not be feasible at all times. Thus, a pragmatic approach to the screening CRF will be taken and trial-specific guidance will be provided to participating sites.

Approach and consent details:
Patients who suffer a traumatic haemo/pneumothorax are patients with varying degrees of capacity to consent to research due to their injuries. Furthermore, the insertion of a chest drain for a traumatic haemo/pneumothorax is often a time-critical intervention due to the impact on patients' breathing and oxygenation. There will be situations where the chest drain treatment cannot be delayed for clinical reasons.

With these two key factors in mind, we will seek written consent from all patients who have the capacity to provide it. In patients without capacity, if intervention is not deemed time critical, we will seek approval from a patient's personal consultee/personal legal representative, either in person or via telephone, using eConsent. If a next of kin is not available, the research team will try to approach one other personal consultee before approaching a nominated consultee. In situations where the chest drain is required in a timeframe that does not allow for approval from a personal consultee/personal legal representative, patients will be enrolled into the trial under waiver of consent (unless the patient is in Scotland, where this is not possible due to the legal framework). Consent in this trial is therefore dependent upon the patient's capacity to consent and the urgency of the chest drain intervention.

We recognise our target population is heterogeneous, which poses challenges in terms of information provision and receiving consent. Patient information material will therefore be available in a variety of formats (for example, but not limited to, paper and video formats), as advised by our patient groups, to facilitate maximal participation across all potentially eligible patients. We will provide the same information for inpatient recruitment beyond the ED (i.e. theatre/ICU/ward) up to 24 hours after presentation to account for the clinical pathway complexities. Patients will be given sufficient time to read/view the information material and ask any questions they may have about the trial. The amount of time available to consider taking part (or to continue participation) will vary. When considering participation in the emergency setting, patient consideration time is estimated to be from one to four hours, as per other trauma-based research.

The potential consent options by capacity and treatment urgency are summarised here:
Pathway A

- Patient has capacity: informed consent provided by the patient
- Pathway A patient loses capacity: Patient provided informed consent but loses capacity during the study, Consultee/Personal Legal Representative approached to provide approval for continued participation.

Pathway B
Patient has no capacity and treatment can be delayed, i.e. intervention is not time critical:

approval from Personal Consultee (England/Wales/N Ireland) or Personal Legal Representative (Scotland) prior to randomisation.

Pathway B patient regains capacity: recruited under Consultee/Personal Legal Representative approval and regains capacity within 7 days of randomisation patient provides approval to continue participation in the study (Recovered Capacity Consent Form).

Pathway B patient does not regain capacity: recruited under Consultee/Personal Legal Representative approval and remains incapacitated 7 days after randomisation. Consultee approves ongoing participation.

Pathway C
Patient has no capacity and treatment cannot be delayed: patient randomised under waiver of consent (patient cannot be enrolled in Scotland).

Pathway C patient regains capacity: recruited under initial waiver of consent and regains capacity within 7 days of randomisation - patient provides approval to continue participation in the study (Recovered Capacity Consent Form). Pathway C patient does not regain capacity: recruited under initial waiver of consent and remains incapacitated 7 days after randomisation - Personal or Nominated Consultee approval.

Randomisation:
Patients will be randomised after traumatic haemo/pneumothorax has been diagnosed on CT, and either consent has been received or deferred consent has been applied and suitably recorded. Participants will be allocated in a 1:1 ratio to either small bore Seldinger or large bore surgical drain. 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 site-level generic log-in details for the secure online randomisation system and study database where applicable.

Randomisation will be stratified by centre and minimised by the presence of predominant pneumothorax or haemothorax at the point of randomisation. Predominance of pneumothorax and haemothorax may be potentially prognostic of outcome, but without robust evidence. Minimisation will allow a balance of these conditions between groups.

Data collection:
Demographic, clinical and other study-related data will be collected and recorded by delegated site team members.

Data will be recorded into paper (and/or online) questionnaires and CRFs and either entered into a trial-specific database at the site by delegated clinical/research site staff, or sent securely (electronically or by post) to the Central Trial Team (Study Office, UoB) for database entry. See Section 18 for further details about data management.

Screening data - Data capture on this CRF will include age (years at time of approach), sex, ethnicity, index of Multiple Deprivation (IMD), preferred language, eligibility details, capacity status of patient, ventilated or unventilated, and type of injury.

Baseline questionnaire - Participants (/consultee) will be asked to complete the Baseline study questionnaire (via paper copy or online), which contains the following PROMS: EQ-5D-5L, Brief Pain Inventory, MRC dyspnoea scale, Impact Events Scale (IES-R).

Baseline CRF - A research nurse, or other delegated site staff member, will complete the Baseline CRF. CRF contents are derived from outcome measures and demographic information.

Follow-up data (30 days and 6 months post randomisation):

30-day questionnaire: Participants will be contacted at 30 days following randomisation to complete a follow-up study questionnaire, which will include questions about pain and function (Brief Pain Inventory), breathlessness (MRC dyspnoea scale), quality of life (EQ-5D-5L), the impact of events scale, and health resource use questionnaire ModRUM.

30-day CRF: data at 30 days will be derived from outcome measures and will be collected from medical notes and GP records. Data will include change in participant's capacity status; all potential major complications of chest drains; total days of pleural drainage; hospital discharge details; total length of hospital stay up to 30 days, mortality data; resource use e.g. hospital data, details of re-attendances to A&E, unplanned re-admissions, critical care (including HDU) length of stay to include initial admission and any additional readmission within 30 days will be recorded onto the CRFs, adverse events.

6-month questionnaire: The 6-month questionnaire will include questions about pain and function (Brief Pain Inventory), breathlessness (MRC dyspnoea scale), quality of life (EQ-5D-5L), the impact of events scale, and the health resource use questionnaire, ModRUM.

6-month CRF: the 6-month CRF contents are derived from outcome measures and will be collected from hospital medical notes and GP records. Data includes all-cause mortality at 6 months post-randomisation; adverse events.

Primary Outcome:
The primary outcome is major complications of chest drains at 30 days post-randomisation. This focuses on the avoidable harm of chest drains and is supported by our PPI groups. They told us minor complications, such as re-suturing, are less important than a major complication, such as an injury to an organ during drain insertion. In the absence of a core-outcome set for chest drains, we adapted a complication reporting tool developed by Aho et al. Complications are divided into insertional, positional, removal, infective, pleural intervention, failure and mortality. Major complications will be measured up to 30 days post randomisation.

Primary outcomes from all participants in the whole study will be independently adjudicated by a blinded expert committee provided with redacted and anonymised clinical vignettes and imaging reports provided by sites. These clinical vignettes and imaging reports will be collected by site staff from clinical records where possible major complications are identified and verified by the local PI. The primary outcome measure will be met for a participant if one individual complication reaches the threshold of a major complication within 30 days of randomisation (or until death, if sooner).

Secondary Outcomes:
The data collection for the secondary outcomes will include items designed to capture clinical effectiveness and patient-reported outcomes. Data collection items include:
• Total number of drain days in either group up to 30 days post randomisation
• All cause mortality and mortality directly attributable to the chest drain/chest injury (independently adjudicated) up to 30 days post randomisation
• Patient-reported outcome measures: pain and function (Brief Pain Inventory), breathlessness Medical Research Council (MRC) dyspnoea scale, trauma (Impact of Events Scale), EQ-5D-5L and resource use at 30 days and 6 months post randomisation

• Total length of hospital stay (hospital and ICU)
• Cost per QALY gained of using small-bore compared to large-bore chest drain at 6 months post randomisation from an NHS and personal social services perspective.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Major complications of chest drains within 30 days of randomisation (or until death, if sooner) measured using an adapted complication reporting tool, which divides complications into insertional, positional, removal, infective, pleural intervention, failure and mortality. Data are independently adjudicated by a blinded expert committee provided with redacted and anonymised clinical vignettes and imaging reports collected by site staff from clinical records provided by sites, where possible major complications are identified and verified by the local PI, at 30 days post randomisation

Key secondary outcome(s))
1. Total number of drain days measured using data collected from records at up to 30 days post randomisation

2. All cause mortality and mortality directly attributable to the chest drain/chest injury (independently adjudicated) measured using data collected from records at up to 30 days post randomisation

3. Pain and function measured using the Brief Pain Inventory (BPI) at baseline, 30 days and 6 months post randomisation

4. Breathlessness measured using Medical Research Council (MRC) dyspnoea scale at baseline, 30 days and 6 months post randomisation

5. Trauma measured using the Impact of Event Scale (IES/IES-R) at baseline, 30 days and 6 months post randomisation

6. Health-related quality of life measured using the EuroQol EQ-5D-5L at baseline, 30 days and 6 months post randomisation

7. Total length of hospital stay (hospital and ICU) measured using data collected from records at one time point

8. Cost per QALY gained of using small-bore compared to large-bore chest drain at 6 months post randomisation from an NHS and personal social services perspective measured using data collected from records at one time point

Completion date
31/03/2029

Eligibility

Key inclusion criteria
Potential participants must satisfy the following criteria to be enrolled in this study:
1. Patients presenting to hospital with a traumatic pneumothorax, haemothorax or

haemopneumothorax (unilateral or bilateral) confirmed on computed tomography (CT) up to 24 hours from presentation;
2. aged, or believed to be aged, 16 years and over
3. AND in whom the treating clinician(s) believes a chest drain is required.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Potential participants who meet any of the following criteria will be excluded from participation:
1. Treating clinician(s) believe injuries are immediately incompatible with life, whereby the patients have no ongoing active management of other injuries or palliation is being undertaken.
2. Patient in cardiorespiratory arrest at the point of randomisation.
3. Retrospective paediatric exclusion if patient confirmed to be less than 16 years.

Date of first enrolment
19/05/2026

Date of final enrolment
31/08/2028

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

Study participating centre

Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

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

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
England
W2 1BL

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
England
BT9 7AB

Study participating centre

North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

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

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
England
NN16 8UZ

Study participating centre
The Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

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

Study participating centre
St George's Hospital
Blackshaw Road
London
England
SW17 0QT

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
Wales
CF14 4HH

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

Study participating centre
Lothian
Waverleygate
2-4 Waterloo PLACE
Edinburgh
City of Edinburgh
Scotland
EH1 3EG

Study participating centre
Freeman Road Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

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

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

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Study participating centre

Great Western Hospital
Marlborough Road
Swindon
England
SN3 6BB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Results and Publications

Individual participant data (IPD) sharing plan
All administrative and clinical study data will be stored in the University of Bristol datacentres using clustered MySQL databases driven by REDCap (https://redcapbrms.bris.ac.uk/redcap/). REDCap is a secure, web-based electronic data capture system designed for the collection of research data. The system has been developed and supported by Vanderbilt University. Bristol

Trials Centre (BTC), at the University of Bristol (UoB), has set up its own infrastructure so that all systems are hosted at and supported by UoB. A Relational Database Management System may be used to provide integration services between administrative and clinical databases. This data will be temporarily stored in a SQL Server system maintained by UoB to support the workflow of the study team. This data will not be made available for analysis.
North Bristol NHS Trust and the Bristol Trials Centre (University of Bristol) are joint data controllers for this study. Data will be held at the University of Bristol and will conform to the University of Bristol Data Security Policy and in Compliance with the General Data Protection Regulation (GDPR) as it applies in the UK, tailored by the Data Protection Act 2018.
Any data held without the written consent of the participant will be pseudo- anonymised and stored as described above.
For monitoring purposes, the CI will allow monitors from the Sponsor team (or delegate), persons responsible for the audit, representatives of the REC and other Regulatory Authorities to have direct access to source data/documents.
The BTC IT Development Team will manage access rights to the data set under instruction from the trial manager (on behalf of the CI). Prospective new users must demonstrate compliance with legal, data protection and ethical guidelines before any data are released.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			16/02/2026	No	No