A trial of common mucoactives used to help airway clearance in patients with respiratory failure requiring mechanical ventilation

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/11/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/11/2021 Last Edited	Ongoing Condition category	Results		
		Individual participant data		
02/07/2025	Respiratory	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

When patients are critically ill, one of the main complications is called acute respiratory failure. This is when a patient's illness causes their lungs to fail to work (lung failure). Patients need to be admitted to the Intensive Care Unit (ICU) and often need to have a breathing machine, or ventilator, to help them breathe and ensure that enough oxygen gets into their blood. However, one problem that can occur as a result of being on a ventilator is difficulty clearing secretions (mucus, or sputum) from the lungs. Not being able to clear secretions from the lungs can make breathing harder, and this may result in developing a lung infection (called ventilator-associated pneumonia).

To reduce the problem of thick secretions, the air coming from the ventilator can have moisture added to it (humidification). Other treatments can include using a suction tube to remove secretions via the breathing tube. Physiotherapists may also use techniques to help clear secretions.

In some cases, medications called 'mucoactives' may be prescribed for patients. Mucoactives are medications that work to help clear secretions from the airways. Two examples of mucoactives are carbocisteine and hypertonic saline. Carbocisteine can help by changing the thickness and stickiness of secretions, which may help clear mucus from the lungs. It is given to patients in the ICU whilst they are on a breathing machine in either liquid form or as a powder dissolved in water, through the patient's feeding tube. Hypertonic saline is salty water that is delivered into the airways via a device called a nebuliser, which turns the salty water into a mist. The mist may stimulate coughing to help clear thick secretions from the lungs.

Carbocisteine and hypertonic saline are commonly given to patients with long-term respiratory conditions such as bronchiectasis or cystic fibrosis, as they have been shown to be helpful. The researchers carried out a survey of UK ICUs and found that about a third of patients on a breathing machine (ventilator) with lung failure were receiving a mucoactive, and carbocisteine and hypertonic saline were the most commonly used. However, it is not known for certain if these medications work in patients admitted to the ICU with lung failure.

The aim of this study is to investigate whether using one, or both, of these mucoactives (carbocisteine and hypertonic saline) really helps patients when they have difficulty clearing secretions, and if as a result, this means patients spend less time on the breathing machine

(ventilator). The researchers will also determine whether these mucoactives can improve other important outcomes for patients during their ICU stay, such as being taken off the breathing machine (ventilator) and having the breathing tube removed (extubation), the need to have the breathing tube put back in (reintubation), and how long patients stayed in the ICU and in hospital. The researchers will record whether patients experience any side effects from the use of these mucoactives.

Who can participate?

Critically ill patients (aged 16 years and over) admitted to the ICU with acute respiratory failure and requiring invasive mechanical ventilation, with secretions that are difficult to clear with usual airway clearance management (as assessed by the treating clinical team).

What does the study involve?

Participants will be put into one of four different groups by chance. The treatments for each group are as follows:

Group 1: Carbocisteine (750 mg, three times daily) plus usual airway clearance management (described below)

Group 2: Hypertonic saline (4 ml, four times daily) plus usual airway clearance management Group 3: Carbocisteine (750 mg, three times daily) and hypertonic saline (4 ml, four times daily) plus usual airway clearance management

Group 4: Usual airway clearance management (including suctioning, heated humidification, respiratory physiotherapy, with or without isotonic saline), and no mucoactive medication.

If a patient is allocated to receive a mucoactive, they will be given this daily for the duration of their stay in intensive care up to a maximum of 28 days (or up to 29 or 30 days if they start breathing without assistance on Day 27 or Day 28 respectively).

The researchers will ask patients to complete a brief questionnaire about their quality of life at discharge from the ICU and after 2 and 6 months. They will ask patients to fill out a questionnaire at 6 months about their healthcare use to find out if there are any differences between the study treatment groups. They will also take samples of airway secretions and blood from patients to determine the ways in which these mucoactives might work, in order to improve lung failure treatments for patients in the future.

What are the possible benefits and risks of participating?

Taking part in this study may contribute to improved treatment of patients with lung failure in the future. Possible disadvantages of taking part are completing the questionnaires at 2 and 6 months after leaving the hospital. However, these questionnaires are sent to patients in the post or by email to make it more convenient for them to complete. While a patient is in the ICU, they may experience some side effects from receiving one or either of the mucoactives. While in the ICU, the doctors will closely monitor a patient's response to the medication, including any side effects. If any side effects occur, the doctors will decide whether it is appropriate to continue the medication.

Where is the study run from? Northern Ireland Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for? May 2021 to October 2025

Who is funding the study?

The National Institute for Health Research Health Technology Assessment Programme (NIHR HTA) (UK)

Who is the main contact? Dr Bronwen Connolly MARCH@nictu.hscni.net

Study website

http://www.nictu.hscni.net/

Contact information

Type(s)

Scientific

Contact name

Dr Bronwen Connolly

ORCID ID

https://orcid.org/0000-0002-5676-5497

Contact details

School of Medicine, Dentistry and Biomedical Sciences Queen's University Belfast 97 Lisburn Road Belfast United Kingdom BT9 7BL +44 (0)28 9097 2215 b.connolly@qub.ac.uk

Type(s)

Public

Contact name

Dr Naomi Dickson

Contact details

Northern Ireland Clinical Trials Unit (NICTU)
7 Lennoxvale
Belfast
United Kingdom
BT9 5BY
+44 (0)28 961 51447
MARCH@nictu.hscni.net

Additional identifiers

EudraCT/CTIS number

2021-003763-94

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

20131DMcA-AS, IRAS 293630, HTA - NIHR130454, CPMS 51165

Study information

Scientific Title

A 2x2 factorial, randomised, controlled, open-label, Phase III, pragmatic, clinical and cost-effectiveness trial with an internal pilot, to determine whether mucoactives (carbocisteine and hypertonic saline) in critically ill patients with acute respiratory failure reduce the duration of mechanical ventilation

Acronym

MARCH

Study objectives

Patients with acute respiratory failure (ARF) who are treated with mucoactives will have a shorter duration of mechanical ventilation compared to patients receiving usual airway clearance management alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/10/2021, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8105, +44 (0)207 104 8103, +44 (0)207 104 8018; leedseast.rec@hra.nhs.uk), REC ref: 21/YH /0234

Study design

2x2 factorial randomized controlled open-label Phase III pragmatic multi-centre clinical- and cost-effectiveness trial with an internal pilot of two medicinal products (i.e. a Clinical Trial of Investigational Medicinal Products)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact MARCH@nictu.hscni.net to request a participant information sheet.

Health condition(s) or problem(s) studied

Acute respiratory failure

Interventions

Current interventions as of 13/11/2023:

Participants will be randomised using an automated web-based or telephone system via randomly permuted blocks in a 1:1:1:1 ratio. There will be stratification by recruitment centre.

Intervention 1: Carbocisteine - 750 mg three times daily, for up to 28 days, delivered systemically, plus usual airway clearance management. (Where unassisted breathing commences on Day 27 or Day 28, carbocisteine will be administered up to Day 29 and Day 30 respectively).

Intervention 2: Hypertonic saline - 4 ml of 6 or 7% concentration, delivered via nebulisation, four times daily, for up to 28 days, plus usual airway clearance management. (Where unassisted breathing commences on Day 27 or Day 28, hypertonic saline will be administered up to Day 29 and Day 30 respectively).

Intervention 3: Carbocisteine and hypertonic saline (as described in 1. and 2.), plus usual airway clearance management.

Comparator: Usual airway clearance management including suctioning, heated humidification (either active heated humidification devices, or passive heat and moisture exchangers), and respiratory physiotherapy; use of isotonic saline may also be used depending on clinician preference.

Previous interventions:

Participants will be randomised using an automated web-based or telephone system via randomly permuted blocks in a 1:1:1:1 ratio. There will be stratification by recruitment centre.

Intervention 1: Carbocisteine - 750 mg three times daily, for up to 28 days, delivered systemically, plus usual airway clearance management. (Where extubation occurs on Day 27 or Day 28, carbocisteine will be administered up to Day 29 and Day 30 respectively).

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Intervention 3: Carbocisteine and hypertonic saline (as described in 1. and 2.), plus usual airway clearance management.

Comparator: Usual airway clearance management including suctioning, heated humidification (either active heated humidification devices, or passive heat and moisture exchangers), and respiratory physiotherapy; use of isotonic saline may also be used depending on clinician preference.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Carbocisteine, hypertonic saline

Primary outcome measure

Duration of mechanical ventilation (in hours), defined (measured) as time from randomisation until first successful unassisted breathing (defined as maintaining unassisted breathing at 48 hours) or death (data obtained from medical notes). This outcome is one of the 'COVenT' core outcomes for trials of interventions intended to modify the duration of mechanical ventilation. To clarify:

- 1. Unassisted breathing is defined as no inspiratory support or extracorporeal lung support
- 2. Success is defined as maintaining unassisted breathing at 48 hours
- 3. Duration includes time receiving extracorporeal lung support, invasive mechanical ventilation and non-invasive ventilation delivering volume or pressure support ventilation
- 4. Duration excludes time receiving high-flow oxygen therapy and continuous positive airway pressure
- 5. Patients with a tracheostomy in situ may still achieve successful unassisted breathing
- 6. Follow-up is to 60 days from randomisation

Secondary outcome measures

Timepoint: In hospital

- 1. Extubation Time (in hours) from randomisation to first successful extubation (success defined as remaining free from endotracheal or tracheostomy tubes at 48 hours); Censored at 60 days; Data obtained from medical notes
- 2. Re-intubation Event of reintubation of endotracheal tube after a planned extubation (censored at hospital discharge); excludes temporary reinsertion of endotracheal tube for procedures only; Censored at 60 days; Data obtained from medical notes
- 3. Respiratory physiotherapy input Occurrence and frequency of airway clearance sessions; Censored at ICU discharge, death, or Day 28 whichever occurs first (where extubation occurs on Day 27 or Day 28, respiratory physiotherapy input will be recorded up to Day 29 and Day 30 respectively); Data obtained from medical notes
- 4. Antibiotic usage Overall dose of individual agents; Censored at ICU discharge, death, or Day 28 whichever occurs first (where extubation occurs on Day 27 or Day 28, antibiotic usage will be recorded up to Day 29 and Day 30 respectively); Data obtained from medical notes
- 5. Duration of ICU and hospital stay Time (in days and hours) from randomisation until the patient first leaves the relevant facility or dies; Censored at 6 months; Data obtained from medical notes
- 6. All-cause mortality Confirmation and cause of death; Data obtained from medical notes 7. Safety Censored at ICU discharge, death, or Day 28 whichever occurs first (where extubation occurs on Day 27 or Day 28, safety outcomes will be recorded up to Day 29 and Day 30

respectively); Data obtained from medical notes; to include the following outcomes:

- 7.1. Clinically important upper gastrointestinal (GI) bleeding due to peptic ulceration confirmed on upper GI endoscopy
- 7.2. Bronchoconstriction requiring nebulised bronchodilators
- 7.3. Ventilator or circuit dysfunction with respiratory deterioration
- 7.4. Hypoxaemia during nebulisation
- 7.5. Hospital resource use Number of days at Level of Care 0/1/2/3; Censored at 6 months; Obtained via data linkage with ICNARC (Intensive Care National Audit & Research Centre) and SICSAG (Scottish Intensive Care Society Audit Group)

Timepoint: Time of consent to continue

Health-related quality of life measured using calculation of quality-adjusted life years (QALYs) via the EQ-5D-5L questionnaire

Timepoint: 60 days

- 1. Health-related quality of life measured using calculation of quality-adjusted life years (QALYs) via the EQ-5D-5L questionnaire
- 2. All-cause mortality Confirmation and cause of death; Data obtained from medical notes

Timepoint: 6 months

- 1. Health-related quality of life measured using calculation of quality-adjusted life years (QALYs) via the EQ-5D-5L questionnaire
- 2. All-cause mortality Confirmation and cause of death; Data obtained from medical notes
- 3. Health service use since hospital discharge measured via a study-specific Health Service Use questionnaire which will collect information on the following categories:
- 3.1. Hospital care: Number of inpatient or day-case hospital admissions; length of stay; the number of hospital outpatient appointments
- 3.2. Emergency care: Number of visits to Emergency Departments; the number of admissions to hospital after a visit to the Emergency Department
- 3.3. Care at a GP surgery, health clinic, or other community setting: the number of appointments; type of professional seen
- 3.4. Health care at home: the number of health care professional visits at home; type of health care professional seen at home
- 3.5. Medication: Name/class of medication. Oxygen use will also be recorded

The secondary outcomes of extubation, re-intubation, duration of ICU and hospital stay, all-cause mortality, and health-related quality of life represent the remaining outcomes in the COVenT core outcome set.

Overall study start date

01/05/2021

Completion date

31/10/2025

Eligibility

Key inclusion criteria

- 1. Aged ≥16 years
- 2. An acute and potentially reversible cause of ARF as determined by the treating physician
- 3. Receiving invasive mechanical ventilation via endotracheal tube or tracheostomy

- 4. Anticipated to remain on invasive mechanical ventilation for at least 48 hours
- 5. Presence of secretions that are difficult to clear with usual airway clearance management (as assessed by the treating clinical team)

Participant type(s)

Patient

Age group

Mixed

Lower age limit

16 Years

Sex

Both

Target number of participants

1956

Total final enrolment

1956

Key exclusion criteria

Current exclusion criteria as of 13/11/2023:

- 1. Pre-existing chronic respiratory condition receiving routine use of any mucoactive
- 2. Mucoactive treatment started more than 24 hours prior to trial enrolment
- 3. Known adverse reaction to either study mucoactive
- 4. Treatment withdrawal expected within 24 hours
- 5. Known pregnancy
- 6. Previous enrolment in the MARCH trial
- 7. Declined consent
- 8. The treating physician believes that participation in the trial would not be in the best interests of the patient

Previous exclusion criteria:

- 1. Pre-existing chronic respiratory condition receiving routine use of any mucoactive
- 2. Mucoactive treatment started more than 24 hours prior to trial enrolment
- 3. Known adverse reaction to either study mucoactive
- 4. Treatment withdrawal expected within 24 hours
- 5. Known pregnancy
- 6. Previous enrolment in the MARCH trial
- 7. Declined consent
- 8. Prisoners
- 9. The treating physician believes that participation in the trial would not be in the best interests of the patient

Date of first enrolment

Date of final enrolment 30/04/2025

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre Royal Liverpool University Hospital

Liverpool University Hospital NHS Foundation Trust Liverpool United Kingdom L7 8XP

Study participating centre Altnagelvin Area Hospital

Glenshane Road Londonderry United Kingdom BT47 6SB

Study participating centre Antrim Area Hospital

45 Bush Rd Antrim United Kingdom BT41 2RL

Study participating centre Barnsley District General Hospital

Pogmoor Road Barnsley United Kingdom S75 2EP

Study participating centre Queen Elizabeth Hospital

University Hospitals Birmingham NHS Foundation Trust Birmingham United Kingdom B15 2GW

Study participating centre Bristol Royal Infirmary

Marlborough Street Bristol United Kingdom BS2 8HW

Study participating centre Royal Infirmary of Edinburgh

51 Little France Crescent Old Dalkeith Road Edinburgh Lothian United Kingdom EH16 4SA

Study participating centre

Freeman Hospital

Newcastle upon Tyne Hospitals NHS Foundation Trust Newcastle upon Tyne United Kingdom NE7 7DN

Study participating centre The Royal Victoria Infirmary

Queen Victoria Road Newcastle upon Tyne United Kingdom TS1 4LP

Study participating centre Glasgow Royal Infirmary

84 Castle Street Glasgow United Kingdom G4 0SF

Study participating centre Gloucester Royal Hospital

Great Western Road Gloucester United Kingdom GL1 3NN

Study participating centre Guy's Hospital

Guy's and St Thomas' NHS Foundation Trust London United Kingdom SE1 9RT

Study participating centre St Thomas' Hospital

Guy's and St Thomas' NHS Foundation Trust London United Kingdom SE1 7EH

Study participating centre Hull Royal Infirmary

Hull University Teaching Hospitals NHS Trust Hull United Kingdom HU3 2JZ

Study participating centre James Cook University Hospital South Took Hospitals NHS Foundation T

South Tees Hospitals NHS Foundation Trust

Middlesbrough United Kingdom TS4 3BW

Study participating centre King's College Hospital King's College Hospital NHS Foundation Trust London United Kingdom SE5 9RS

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE1 5WW

Study participating centre Medway Maritime Hospital Medway NHS Foundation Trust Gillingham United Kingdom ME7 5NY

Study participating centre
Morriston Hospital NHS Trust
Heol Maes Eglwys
Morriston
Swansea
United Kingdom
SA6 6NL

Study participating centre
Musgrove Park Hospital
Somerset NHS Foundation Trust
Taunton
United Kingdom
TA1 5DA

Study participating centre Queen's Medical Centre

Nottingham University Hospital NHS Trust Nottingham United Kingdom NG7 2UH

Study participating centre Pinderfields Hospital

The Mid Yorkshire Hospitals NHS Trust Wakefield United Kingdom WF1 4DG

Study participating centre Poole Hospital

University Hospitals Dorset NHS Foundation Trust Poole United Kingdom BH15 2JB

Study participating centre Queen Elizabeth Hospital

Lewisham and Greenwich NHS Trust London United Kingdom SE13 6LH

Study participating centre University Hospital Lewisham

Lewisham and Greenwich NHS Trust London United Kingdom SE13 6LH

Study participating centre Rotherham District General Hospital The Rotherham NHS Foundation Trust

Rotherham United Kingdom S60 2UD

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

Study participating centre Royal Bournemouth Hospital

Castle Lane East Bournemouth United Kingdom BH7 7DW

Study participating centre Royal Cornwall Hospital

Royal Cornwall Hospitals NHS Trust Truro United Kingdom TR1 3LJ

Study participating centre Aintree Hospital

Liverpool University Hospital NHS Foundation Trust Liverpool United Kingdom L9 7AL

Study participating centre The Royal Oldham Hospital

Rochdale Road Oldham United Kingdom OL1 2JH

Study participating centre Royal Stoke University Hospital

University Hospitals of North Midlands NHS Trust Stoke-on-Trent United Kingdom ST4 6QG

Study participating centre Royal United Hospital Bath

Royal United Hospitals Bath NHS Foundation Trust Bath United Kingdom BA1 3NG

Study participating centre Royal Victoria Hospital

Belfast Health and Social Care Trust Belfast United Kingdom BT12 6BA

Study participating centre Salford Royal Hospital

Salford Royal NHS Foundation Trust Manchester United Kingdom M6 8HD

Study participating centre Birmingham City Hospital

Sandwell and West Birmingham Hospitals NHS Trust Birmingham United Kingdom B18 7QH

Study participating centre Southmead Hospital

North Bristol NHS Trust Bristol United Kingdom BS10 5NB

Study participating centre Sunderland Royal Hospital

South Tyneside and Sunderland NHS Foundation Trust Sunderland United Kingdom SR4 7TP

Study participating centre Watford General Hospital

West Hertfordshire Hospitals NHS Trust Watford United Kingdom WD18 0HB

Study participating centre Manchester Royal Infirmary

Manchester University Hospitals NHS Foundation Trust Manchester United Kingdom M13 9WL

Study participating centre York Hospital

York and Scarborough Teaching Hospitals NHS Foundation Trust York United Kingdom YO31 8HE

Study participating centre Royal Hampshire County Hospital

Romsey Road Winchester United Kingdom SO22 5DG

Study participating centre Ipswich Hospital Heath Road

Ipswich United Kingdom IP4 5PD

Study participating centre Royal Preston Hospital

Lancashire Teaching Hospitals NHS Foundation Trust Preston United Kingdom PR2 9HT

Study participating centre Golden Jubilee National Hospital

National Waiting Time Centre Board Clydebank United Kingdom G81 4DY

Study participating centre University Hospital Coventry

University Hospitals Coventry and Warwickshire NHS Trust Coventry United Kingdom CV2 2DX

Study participating centre The Grange University Hospital

Caerleon Road Cwmbran United Kingdom NP44 8YN

Study participating centre Queen Alexandra Hospital

Portsmouth Hospitals NHS Trust
Portsmouth
United Kingdom
PO6 3LY

Study participating centre Wythenshawe Hospital

Manchester University NHS Foundation Trust Manchester United Kingdom M23 9LT

Study participating centre North Manchester General Hospital

Manchester University NHS Foundation Trust Manchester United Kingdom M8 5RB

Study participating centre Belfast City Hospital

Belfast Health and Social Care Trust Belfast United Kingdom BT9 7AB

Study participating centre Sandwell General Hospital

Sandwell and West Birmingham Hospitals NHS Trust West Bromwich United Kingdom B71 4HJ

Study participating centre Addenbrookes Hospital

Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre Heartlands Hospital

Bordesley Green East Bordesley Green Birmingham United Kingdom B9 5ST

Study participating centre Chesterfield Royal Hospital

Chesterfield Road Calow Chesterfield United Kingdom S44 5BL

Study participating centre John Radcliffe Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Victoria Hospital

Hayfield Road Kirkcaldy United Kingdom KY2 5AH

Study participating centre Royal Devon and Exeter Hospital

Royal Devon & Exeter Hospital Barrack Road Exeter United Kingdom EX2 5DW

Study participating centre Lincoln County Hospital

Greetwell Road Lincoln United Kingdom LN2 5QY

Study participating centre Queen Elizabeth University Hospital

1345 Govan Road Glasgow United Kingdom G51 4TF

Study participating centre Derriford Hospital

Derriford Road Plymouth United Kingdom PL6 8DH

Study participating centre William Harvey Hospital

Kennington Road Willesborough Ashford United Kingdom TN24 0LZ

Study participating centre Yeovil District Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre University Hospital Monklands

Monkscourt Ave Airdrie United Kingdom ML6 0JS

Study participating centre

West Suffolk Hospital

Hardwick Lane Bury St. Edmunds United Kingdom **IP33 2QZ**

Study participating centre Northern General Hospital

Northern General Hospital NHS Trust C Floor, Huntsmnan Building Herries Road Sheffield United Kingdom **S5 7AU**

Study participating centre Royal Hallamshire Hospital

Glossop Road Sheffield United Kingdom S10 2JF

Study participating centre Wrexham Maelor Hospital

Croesnewydd Road Wrexham Technology Park Wrexham United Kingdom **LL13 7TD**

Study participating centre Glan Clwd Hospital

Ysbyty Glan Clwydd Bodelwyddan Rhyl United Kingdom LL18 5UJ

Study participating centre Aberdeen Royal Infirmary

Foresterhill Road

Aberdeen United Kingdom AB25 2ZN

Study participating centre Bedford Hospital

Kempston Road Bedford United Kingdom MK42 9DJ

Study participating centre University College London Hospital

250 Euston Road London United Kingdom NW1 2PG

Study participating centre Torbay Hospital

Newton Road Torquay United Kingdom TQ2 7AA

Study participating centre Royal Free Hospital

Royal Free Hospital Pond Street London United Kingdom NW3 2QG

Study participating centre Warrington Hospital

Lovely Lane Warrington United Kingdom WA5 1QG

Study participating centre Northern Devon District Hospital

Raleigh Park Barnstaple United Kingdom EX31 4JB

Sponsor information

Organisation

Belfast Health and Social Care Trust

Sponsor details

Research Office
2nd Floor King Edward Building
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA
+44 (0)28 961 56057
Alison.Murphy@belfasttrust.hscni.net

Sponsor type

Hospital/treatment centre

Website

http://www.belfasttrust.hscni.net/

ROR

https://ror.org/02tdmfk69

Funder(s)

Funder type

Government

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

Publication and dissemination plan

The researchers will publish the trial protocol and statistical analysis plan to ensure transparency in their methodology. The study findings will be presented at national and international meetings with abstracts online. Presentation at these meetings will ensure that results and any implications are rapidly disseminated to the wider UK intensive care community.

In accordance with the open-access policies proposed by the NIHR the researchers plan to publish the clinical findings of the trial as well as a separate paper describing the cost-effectiveness in the NHS setting in high quality peer-reviewed open access (e.g. including via PubMed Central) journals. A final report will also be published in the NIHR HTA journal.

Due to limited resources, it will not be possible to provide each patient with a personal copy of the results of the trial. However, upon request, patients involved in the trial will be provided with a lay summary of the principal study findings.

The most significant results will be communicated to the wider public through media releases. An ongoing update of the trial will also be provided on the CTU website.

Following the publication of the primary and secondary outcomes there may be scope to conduct additional analyses on the data collected. In such instances formal requests for data will need to be made in writing to the Chief Investigator or Co-Chief Investigator via the Clinical Trials Unit, who will discuss this with the Sponsor. The study will comply with the good practice principles for sharing individual participant data from publicly funded clinical trials and data sharing will be undertaken in accordance with the required regulatory requirements. In the event of publications arising from such analyses, those responsible will need to provide the Chief Investigator or Co-Chief Investigator with a copy of any intended manuscript for approval prior to submission.

Intention to publish date

30/11/2026

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request following the publication of the primary and secondary outcomes. Formal requests for data should be made in writing to Prof. Danny McAuley (Chief Investigator) or Dr Bronwen Connolly (Co-Chief Investigator) via the Trial Manager, Caroline Wilson (MARCH@nictu.hscni.net). Requests will be reviewed on a case by case basis in collaboration with the Sponsor.

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		10/04/2025	17/06/2025	Yes	No