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

Submission date
11/11/2021

Recruitment status
No longer recruiting

Registration date
25/11/2021

Overall study status
Completed

Last Edited
30/07/2026

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 April 2026

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

Contact information

Type(s)
Scientific

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Type(s)
Public

Contact name
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MARCH@nictu.hscni.net

Additional identifiers

Clinical Trials Information System (CTIS)
2021-003763-94

Integrated Research Application System (IRAS)
293630

Central Portfolio Management System (CPMS)

51165

National Institute for Health and Care Research (NIHR)
130454

Protocol serial number
20131DMcA-AS

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

Primary study design
Interventional

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)

Study type(s)
Treatment

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.

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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(s)

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

Key secondary outcome(s)

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.

Completion date
01/04/2026

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit

120 Years

Sex
All

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

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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
17/02/2022

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospital NHS Foundation Trust
Liverpool
England
L7 8XP

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Londonderry
Northern Ireland
BT47 6SB

Study participating centre
Antrim Area Hospital
45 Bush Rd
Antrim
Northern Ireland
BT41 2RL

Study participating centre
Barnsley District General Hospital
Pogmoor Road
Barnsley
England
S75 2EP

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Birmingham
England
B15 2GW

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
England
BS2 8HW

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
Scotland
EH16 4SA

Study participating centre
Freeman Hospital
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle upon Tyne
England
NE7 7DN

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

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester

England
GL1 3NN

Study participating centre
Guy's Hospital
Guy's and St Thomas' NHS Foundation Trust
London
England
SE1 9RT

Study participating centre
St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
London
England
SE1 7EH

Study participating centre
Hull Royal Infirmary
Hull University Teaching Hospitals NHS Trust
Hull
England
HU3 2JZ

Study participating centre
James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Middlesbrough
England
TS4 3BW

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

Study participating centre

Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Leicester
England
LE1 5WW

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

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

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

Study participating centre
Queen's Medical Centre
Nottingham University Hospital NHS Trust
Nottingham
England
NG7 2UH

Study participating centre
Pinderfields Hospital
The Mid Yorkshire Hospitals NHS Trust
Wakefield
England
WF1 4DG

Study participating centre
Poole Hospital
University Hospitals Dorset NHS Foundation Trust
Poole
England
BH15 2JB

Study participating centre
Queen Elizabeth Hospital
Lewisham and Greenwich NHS Trust
London
England
SE13 6LH

Study participating centre
University Hospital Lewisham
Lewisham and Greenwich NHS Trust
London
England
SE13 6LH

Study participating centre
Rotherham District General Hospital
The Rotherham NHS Foundation Trust
Rotherham
England
S60 2UD

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

Study participating centre
Royal Bournemouth Hospital
Castle Lane East

Bournemouth
England
BH7 7DW

Study participating centre
Royal Cornwall Hospital
Royal Cornwall Hospitals NHS Trust
Truro
England
TR1 3LJ

Study participating centre
Aintree Hospital
Liverpool University Hospital NHS Foundation Trust
Liverpool
England
L9 7AL

Study participating centre
The Royal Oldham Hospital
Rochdale Road
Oldham
England
OL1 2JH

Study participating centre
Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust
Stoke-on-Trent
England
ST4 6QG

Study participating centre
Royal United Hospital Bath
Royal United Hospitals Bath NHS Foundation Trust
Bath
England
BA1 3NG

Study participating centre
Royal Victoria Hospital
Belfast Health and Social Care Trust
Belfast
Northern Ireland
BT12 6BA

Study participating centre
Salford Royal Hospital
Salford Royal NHS Foundation Trust
Manchester
England
M6 8HD

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Bristol
England
BS10 5NB

Study participating centre
Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust
Sunderland
England
SR4 7TP

Study participating centre
Watford General Hospital
West Hertfordshire Hospitals NHS Trust
Watford
England
WD18 0HB

Study participating centre
Manchester Royal Infirmary
Manchester University Hospitals NHS Foundation Trust
Manchester
England
M13 9WL

Study participating centre
York Hospital
York and Scarborough Teaching Hospitals NHS Foundation Trust
York
England
YO31 8HE

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
England
SO22 5DG

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
England
IP4 5PD

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Preston
England
PR2 9HT

Study participating centre
Golden Jubilee National Hospital
National Waiting Time Centre Board
Clydebank
Scotland
G81 4DY

Study participating centre
University Hospital Coventry
University Hospitals Coventry and Warwickshire NHS Trust

Coventry
England
CV2 2DX

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

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Portsmouth
England
PO6 3LY

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Manchester
England
M23 9LT

Study participating centre
North Manchester General Hospital
Manchester University NHS Foundation Trust
Manchester
England
M8 5RB

Study participating centre
Belfast City Hospital
Belfast Health and Social Care Trust
Belfast
Northern Ireland
BT9 7AB

Study participating centre
Sandwell General Hospital
Sandwell and West Birmingham Hospitals NHS Trust
West Bromwich
England
B71 4HJ

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
England
B9 5ST

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

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

Study participating centre
Victoria Hospital
Hayfield Road

Kirkcaldy
Scotland
KY2 5AH

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
Scotland
G51 4TF

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

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
England
TN24 0LZ

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
England
BA21 4AT

Study participating centre
University Hospital Monklands
Monkscourt Ave
Airdrie
Scotland
ML6 0JS

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

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
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S10 2JF

Study participating centre

Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
Wales
LL13 7TD

Study participating centre
Ysbyty Glan Clwyd
Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
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LL18 5UJ

Study participating centre
Aberdeen Royal Infirmary
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AB25 2ZN

Study participating centre
Bedford Hospital
Kempston Road
Bedford
England
MK42 9DJ

Study participating centre
University College London Hospital
250 Euston Road
London
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NW1 2PG

Study participating centre
Torbay Hospital
Newton Road
Torquay

England
TQ2 7AA

Study participating centre
Royal Free Hospital
Royal Free Hospital
Pond Street
London
England
NW3 2QG

Study participating centre
Warrington Hospital
Lovely Lane
Warrington
England
WA5 1QG

Study participating centre
Northern Devon District Hospital
Raleigh Park
Barnstaple
England
EX31 4JB

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Sponsor information

Organisation
Belfast Health and Social Care Trust

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

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, Lynn Murphy (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?

Results article	10/06/2026	11/06/2026	Yes	No
Protocol article	10/04/2025	17/06/2025	Yes	No
HRA research summary		28/06/2023	No	No
Study website	11/11/2025	11/11/2025	No	Yes