ISRCTN24603037 https://doi.org/10.1186/ISRCTN24603037

Is it possible to complete a large study to see whether using a cough device in ICU can help remove breathing support in ICU patients?

Submission date
03/05/2022

Recruitment status
No longer recruiting

Registration date
16/05/2022

Overall study status
Completed

Last Edited
18/09/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Intensive Care Unit (ICU) patients often require breathing support from a machine and breathing tube. Most adults are successfully removed from this support (extubation). However, 10-20% of patients are unable to breathe by themselves after tube removal and it needs to be put back in. One main reason for this is because patients are unable to cough well enough to clear mucus from their airway. This can lead to worse patient outcomes, including increased length of hospital stay and risk of death.
To help with successful extubation, physiotherapists can use a device to help patients cough and clear phlegm. The cough device works by blowing air into the patients lungs followed by quickly sucking it out. This device can be used before and after extubation. The cough device has only recently been used in ICU and there are no studies exploring patients and healthcare professional's experiences of its use.
The aim is to find out if it is possible to complete a large study to see whether using a cough device in ICU can help remove breathing support in ICU patients.

Who can participate?
Patients aged 16 years or above, who have been receiving mechanical ventilation.

What does the study involve?
Stage 1: A small (50 participants), single site study. The study will tell us whether it is possible to recruit patients and whether they remain in the study. It will also look at the safety of the cough device (most safety data is from other hospital settings).
Permission (consent) for the study will likely be from family members or healthcare professional as patients will still be using the breathing machine when they join the study. Patients will be asked for consent for ongoing study participation once they are able.
Stage 2: Interviews with patients/clinicians involved in the study will seek experiences of using the cough device. Separate patient consent will be sought. Clinicians will be specifically approached for inclusion.

What are the possible benefits and risks of participating?
It is not known whether the cough device will help patients in the trial, but the trial and patient interviews will provide information which could enable patients to benefit in the future. We do not foresee or anticipate any significant risk to you in taking part in this project. Reported unwanted side effects from using the cough device are extremely rare and include short term changes to your blood pressure, heart rate and oxygen levels. Your tolerance of the device will be monitored throughout by bedside clinicians. If, however, you feel uncomfortable at any time you can ask for the treatment to stop.
If you need any support during or after the interview then the researchers will be able to put you in touch with suitable support agencies. The project team are experienced in conducting interviews, which have been designed by a team of people with expertise in the subject area.

Where is the study run from?
University Hospitals Bristol and Weston NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2020 to December 2023

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

Who is the main contact?
Ema Swingwood, ema.swingwood@uwe.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Ema Swingwood

ORCID ID
https://orcid.org/0000-0003-1507-6748

Contact details
Adult Therapies A804
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW
+44 117 3282232
ema.swingwood@uwe.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

303674

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52178, NIHR300504, IRAS 303674

Study information

Scientific Title
A feasibility study examining the use of Mechanical Insufflation Exsufflation to promote extubation success in adult intensive care

Acronym
MERIT

Study objectives
To find out if it is possible to complete a large study to see whether using a cough device in ICU can help remove breathing support in ICU patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2022, Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 22/YH/0042

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Resuming self breathing after breathing support in ICU

Interventions
This study is a single centre, parallel group, randomised controlled trial with economic scoping, nested exploratory physiology study and nested qualitative study. The study protocol has been developed by the CI, associated research team and patient advisory group with extensive peer review from the funding body.

The study aims to find out if it is possible to complete a large study to see whether using a cough device in ICU can help remove breathing support in ICU patients.
There are 2 stages to the study:

1. Feasibility intervention trial
2. Semi structured interviews

Randomisation: Following informed consent/advice for study participation, participants will be randomized into a study arm to either A-control arm (standard care) or B-intervention arm (cough device plus standard care). Randomisation will occur using an online system called 'Sealed envelopes'.

Baseline data collection: Pre-designed data collection forms will be used during the course of the study. Baseline demographic data recoded for all participants includes age, gender, predicted body weight, history of chronic lung disease, smoking history, reason for intubation, date of hospital and ICU admission, date of intubation, APACHE II score, baseline ventilator settings and airway type and size.

Trial treatments:
A-Control Arm (standard care)- Patients will receive standard care including ventilation, weaning, standard physiotherapy techniques such as positioning, manual techniques, manual/ventilator hyperinflation, suctioning, and nebulisers. Respiratory physiotherapy treatments will vary across patients as treatments will be delivered at the discretion of the treating physiotherapist based on individual assessment and not be protocolised. Decisions to remove breathing support (extubate) and re-intubate will be made by the attending physician with reason(s) documented. Clinical data collection will occur during physiotherapy intervention sessions in the 24hours preceding extubation and up to 48 hours post extubation.
B-Intervention Arm (Cough device plus standard care). The cough device (MI-E) works by blowing air into the patients lungs followed by quickly sucking it out. This device can be used before and after extubation. The device is reusable between patients with single patient use circuits, filters and interface (mouthpiece, facemask and flexible catheter mount).

Whilst intubated (breathing machine and breathing tube in place), treatment will include a minimum of two MI-E sessions via the breathing tube prior to the breathing tube being removed. MI-E settings will be individualised to each patient based on current ventilator settings, patient tolerance, chest expansion and secretion clearance. There is a guide in place for clinicians to use. After breathing tube removal (extubation) (and up to 48hrs), patients will receive MI-E delivered via facemask or mouthpiece up to 2 times/day with MI-E settings individualised and set according to patient tolerance, chest wall expansion and secretion clearance (as assessed by treating physiotherapist).

For both treatment arms, data collection will take place during the 24 hours prior to extubation and for 48hours following extubation. Data collection will include physiotherapy treatment interventions completed, use of additional respiratory support (tracheostomy, high flow oxygen therapy, non invasive ventilation), lung ultrasound score, pain score, cardiovascular parameters (heart rate and rhythm, systolic and diastolic blood pressure), ventilatory parameters (ventilator settings, lung compliance, airway resistance), respiratory parameters (respiratory rate, peripheral oxygen saturations, end inspiratory and expiratory lung volumes).
We will also record resource use during the ICU admission and will include staffing requirements (time duration, grade AfC), consumable use and the cost of obtaining and maintaining the device. Patient related resource use will include suction frequency (over a 24-hour period), antibiotic use, physiotherapy oncall use (planned and unplanned), ICU LOS, ICU re-admission and hospital LOS.
A quality of life measure (EQ-5D-5L) questionnaire will be collected retrospectively at recruitment for pre-admission and at six months post ICU discharge.

Patients from the intervention (cough device) arm of the study will be eligible for inclusion into the smaller physiology study which involves some additional data collection using Electrical Impedance Tomography (EIT). EIT is a noninvasive, radiation free technique used at the bedside to provide information about lung volumes. The technique is used clinically and in ICU research studies. We will use this technique to establish what happens to lung volumes as the positive and negative pressure breaths are delivered by the cough device. We plan to recruit 5-10 participants for additional data collection. Consent processes are as per the main trial protocol.

Qualitative interviews: Interviews with some patients/clinicians involved in the study will seek experiences of using the cough device. Eligible clinicians will need to be either a doctor, physiotherapist or nurse by profession, be working as a permanent staff member at the study site and have participated in the study within the last 4 weeks. Patients/personal consultees are eligible for study inclusion if they have been approached for informed consent/advice. Patients will be excluded if they are non-English speaking or have impaired understanding, or if they have no recall of their ICU stay or MI-E use.
All interviews will be completed virtually via an online platform (Microsoft Teams) or telephone (interviewee preference) and digitally recorded (via an encrypted Dictaphone). Patients and consultees recruited into the study will be approached for consent into this phase once the patient has been discharged from ICU but remains in hospital.
Interviews will take place within 4-6 weeks of ICU discharge-this may therefore be whilst the patient is still in hospital or at home.
Participants will have received a copy of the consent form with the study information. The lead interviewer will run through this at the start of the interview and the participant will be asked to provide verbal (recorded) consent for each point on the consent form.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes measured at the end of the study:
1. Proportion of eligible patients approached, consented and randomised measured using screening log and randomization records
2. Proportion of MI-E treatment sessions completed measured using case report form
3. Proportion of recruited patients with all outcome measures recorded measured using case report form
4. Attrition (participant withdrawal and loss to follow up) measured using case report form and withdrawal records
5. Acceptability of trial processes to participants and clinicians measured using qualitative interviews, acceptability of intervention measure (AIM)/Intervention appropriate measure (IAM) /feasibility of intervention measure (FIM)
6. Acceptability of outcome measures to participants and clinicians measured using qualitative interviews

Key secondary outcome(s))
1. Resource use (use of HFNC, NIV, trachy; MI-E equipment, staff grade and time) at end of each treatment intervention and per 24hr period
2. Lung ultrasound score pre intervention and 5mins post intervention
3. Pain is measured using the numeric rating scale and/or critical care pain observation tool (CPOT)
4. QOL is measured using the EQ-5D-5L at 6 months following ICU discharge
5. Re-intubation rate will be calculated at 48hours post extubation

6. Mortality will be calculated at 60days post randomisation
7. Cardiovascular parameters (heart rate, systolic and diastolic blood pressure) measured at pre intervention, intervention end and 5mins post intervention
8. Ventilator/respiratory parameters (lung resistance/compliance, respiratory rate, peripheral oxygen saturations) measured pre intervention, intervention end and post extubation)
9. Adverse events (occurrence frequency of HR, SBP, DBP increase/decrease >20% baseline; arrhythmia requiring intervention; pneumothorax; acute desaturation to <85% or >10% below baseline; cardiopulmonary arrest; accidental extubation) measured at end of intervention and 5 mins post intervention end

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Adult (>=16 years)
2. Expected to require invasive mechanical ventilation for >48hrs
3. Clinician identified pre-extubation problems with secretion management defined as poor /weak cough effort (cough peak flow <60L/min) and/or secretion load that are difficult to clear with usual airway clearance management (as assessed by the treating clinical team)
4. Identified as 'ready to wean or weaning' by the treating clinical team (on a spontaneous mode of ventilation for example Continuous Positive Airway Pressure (CPAP); Assisted Spontaneous Breathing (ASB); Pressure Support Ventilation (PSV); Airway Pressure Release Ventilation (APRV) (with spontaneous effort).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Positive End Expiratory Pressure (PEEP) >10
2. Fraction of Inspired Oxygen (FiO2) >0.7
3. Hemodynamic/Cardiovascular instability (i.e. noradrenaline >0.25mg/kg, arrhythmias requiring intervention)
4. Recent undrained pneumothorax (current admission with no chest drain in situ);

5. Unable to continue to use MI-E post extubation (i.e. contraindications to facemask use-facial /cranial trauma, recent facial surgery; active upper gastrointestinal bleeding/uncontrolled vomiting; recent upper abdominal/thoracic surgery with at risk anastomosis)
6. Pre-existing neuromuscular respiratory condition
7. Pre-existing routine use of MI-E in the community
8. Patients with pre-existing permanent tracheostomy
9. Treatment withdrawal expected within 24hrs or not expected to survive
10. Re-admission to ICU following index admission
11. Previous MERIT trial participation

Date of first enrolment
11/07/2022

Date of final enrolment
11/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

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

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Chief Investigator Ema Swingwood (ema.swingwood@uwe.ac.uk). All data will be anonymised for which consent has been gained. Data will only be provided for purposes of research studies. Data will be available once it has been analysed and published by the current research team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/07/2023	25/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes