ISRCTN15425727 https://doi.org/10.1186/ISRCTN15425727

Comparison of the effectiveness of two different respiratory exercise training methods in prolonged ventilated patients

Submission date
24/06/2020

Recruitment status
No longer recruiting

Registration date
05/07/2020

Overall study status
Completed

Last Edited
21/10/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Reduced breathing muscle performance contributes to the prolonged duration of mechanical ventilation (external breathing machine support) and makes it difficult to come off from the machine. Reduced breathing muscle function also impacts on non-ventilatory functions of the respiratory system including coughing and swallowing function.
We are planning to conduct a study in prolonged ventilated patients(patients on external breathing machine support) to find out the impact of different types of resistance breathing exercises. These are used in some intensive care units to strengthen breathing muscles worldwide. This study will help us to determine whether this resistance breathing exercises during prolonged ventilation are necessary or not.

Who can participate?
Patients requiring breathing support with a ventilator (external breathing machine) for more than 5 days who are suitable will be included in the study following a discussion with consultant anesthetist and clinical nurse manager.

What does the study involve?
This proposed study plans to monitor and manage breathing muscle dysfunction with multiple tests of strength and endurance and with a dual valve CE marked low-cost device that will be adapted in a novel way to train breathing muscles which help to breathe in and out. Patients will undergo four sets of ten breaths twice a day for two weeks duration with CE marked device. The strength and endurance tests of breathing muscles will be done before and after exercise training.

What are the possible benefits and risks of participating?
Benefits:
The results will help us to determine which exercises help to improve weak respiratory muscle function.
Risks:
There are no anticipated risks with this study. Respiratory assessments are commonly used in

physiotherapy. The tests are not invasive. None of the assessments have the potential to cause harm. Different exercises being compared in this study. They are both in line with the intended use of the CE marked device. We will find out from this study if there are any differences between these different exercises in improving respiratory muscle function.

Where is the study run from?
Connolly Hospital Blanchardstown (Ireland)

When is the study starting and how long is it expected to run for?
June 2019 to December 2021

Who is funding the study?
Anglia Ruskin University (UK)

Who is the main contact?
Mr Atchuta Kishore Kothapalli, kishore.kothapalli@hse.ie

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparing effectiveness REspiratory Muscle Dysfunction Interventions IMT versus RMT study in prolonged ventilated patients

Acronym
REMDI

Study objectives
Can respiratory (inspiratory and expiratory) muscle training be feasible and more effective compared to inspiratory muscle training alone in prolonged ventilated patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2019, Ethics Committee (Connolly Hospital Blanchardstown, Dublin 15, D15 X40D, Republic of Ireland; +353 18213844; nancy.mcguirk@hse.ie), ref: none provided

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory muscle dysfunction in prolonged ventilated patients

Interventions
Participants will either receive:
1. 2 weeks of inspiratory muscle training, or
2. 2 weeks of both expiratory and inspiratory muscle training

The same CE marked device is set at 50% threshold to train either:
1. Maximum inspiratory pressure (MIP), or
2. Both MIP and Maximum Expiratory Pressure (MEP). Both groups will undergo four sets of ten breaths twice a day for two weeks

Randomisation. To minimise selection bias during randomisation the physiotherapist who is not involved in the study and will have no interaction with any of the trial participants will randomise with concealed randomisation and will have no interaction with any of the trial participants.

There are two data collection points 1) at baseline and 2) at 2 weeks after exercise

Intervention Type
Behavioural

Primary outcome measure
Maximum Inspiratory Pressure (MIP) measured using CE marked Micro RPM (Respiratory Pressure Monitor) at pre-(baseline) and post-intervention (2 weeks). 3 trials are taken and the highest value will be used.

Secondary outcome measures
Measures will be performed pre-(baseline) and post-intervention (2 weeks):
1. Maximum Expiratory Pressure (MEP) will be measured using a pressure manometer - 3 trials are taken and the highest value will be used
2. Cough strength will be measured using a semi-quantitative cough strength score
3. Fatigue resistance index will be measured using the ratio of MIP, post-training with Inspiratory Muscle Trainer/MIP pre-training.
4. Rectus abdominis muscle thickness assessment will be measured using a diagnostic ultrasound machine
5. Hand dynamometry will be measure peripheral muscle function – 3 trials are taken on the participants dominant hand and the highest value will be used

Overall study start date
18/06/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Adult patients 18 years or above admitted to general critical care unit and required mechanical ventilation support for more than five days
2. Patients who can respond to the verbal command and can tolerate breathing exercises such as “deep breath in and out”
3. Richmond Agitation-Sedation Scale score 0

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Medically unstable during critical care admission and prolonged ventilation period before training
2. Use of more than minimal continuous infusion inotropic agents
3. Contraindication to disconnect the patient from the mechanical ventilator for RMT treatment or IMT treatment
4. Acute coronary artery disease
5. Thoracic contraindications

Date of first enrolment
06/09/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Ireland

Study participating centre
Connolly Hospital Blanchardstown
Mill Rd
Abbotstown
Dublin
Ireland
D15 X40D

Sponsor information

Organisation
Connolly Hospital Blanchardstown

Sponsor details

Mill Rd
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Ireland
D15 X40D
+353 1 8213844
therapy.chb@hse.ie

Sponsor type
Hospital/treatment centre

Website
https://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/connolly

ROR
https://ror.org/03h5v7z82

Organisation
Anglia Ruskin University

Sponsor details
East Road
Cambridge
England
United Kingdom
CB11PT
+44 (0)1223 692362
frep-fhems@anglia.ac.uk

Sponsor type
University/education

Website
http://www.anglia.ac.uk/

ROR
https://ror.org/0009t4v78

Funder(s)

Funder type
University/education

Funder Name
Anglia Ruskin University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study participants will be offered a summary of the study's results, by post, at the end of the study. The results of this study will be reported via at least one peer-reviewed medical journal. Research findings will also be disseminated at a scientific conference. We will not be naming any organisations (i.e. Hospital) in the report although the principal investigator works at this institution (with is usually named on reports). The hospital ethics committee has given permission to conduct the research.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Raw data will be available for 5 years from when the results are submitted for publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			21/10/2022	No	No
Protocol file			21/10/2022	No	No