ISRCTN51523311 https://doi.org/10.1186/ISRCTN51523311

# The effectiveness of intensive chest physiotherapy for patients on mechanical ventilation in ICU

**Submission date**
05/07/2016

**Recruitment status**
No longer recruiting

**Registration date**
21/07/2016

**Overall study status**
Completed

**Last Edited**
04/01/2021

**Condition category**
Respiratory

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

## Plain English summary of protocol

Background and study aims
When a patient is in an intensive care unit (ICU), they may require need help breathing. This is often done using a process called intubation, in which a flexible plastic tube is passed down the throat into the windpipe in order to keep the airways open. The tube is then connected to a breathing machine which passes air into and out of the lungs (mechanical ventilation). When the patient has recovered enough for the tube to be removed (extubation), in some cases this is unsuccessful (extubation failure) and the tube needs to be put back in (reintubation). Extubation failure can lead to a long hospital stay, higher death rate, and increases the chance that the patient will need an operation called a tracheostomy (an opening created at the front of the neck so a tube can be inserted into the windpipe). Chest physiotherapy (CPT) can help to reduce the chance of this, as it prevents fluid from building up in the lungs which can lead to complications. However, few studies have been done looking at the relationship between CPT and extubation failure. The aim of this study is to investigate whether CPT reduces the rate of extubation failure.

Who can participate?
Adults admitted to the Landseed Hospital Intensive Care Unit who require mechanical ventilation for at least 48 hours.

What does the study involve?
Two groups of participants take part in this study. The first group of participants does not actively take part but are patients who previously received standard nursing care while in ICU in 2015. Their medical records are reviewed in order to assess the extubation failure rate and the amount successfully extubated (extubation outcomes). The second group is currently on ICU and takes part in a chest physiotherapy program. This consists of various training exercises aiming to strengthen the muscles involved in breathing, and the removal of mucous from the airways. Treatment takes place in 30-40 minute sessions once a day, five times a week, until the patient is discharged from ICU. At the end of the study, the extubation outcomes are compared between the groups to find out whether the treatment helped reduce the rate of extubation failure.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved to those participating in this study.

Where is the study run from?
Landseed Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
October 2014 to October 2015

Who is funding the study?
Landseed Hospital (Taiwan)

Who is the main contact?
Mr Tsung-Hsien Wang
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# Contact information

### Type(s)
Public

### Contact name
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

## Scientific Title
Chest physiotherapy to improve extubation outcomes for critically ill patients with mechanical ventilation in ICU

## Study objectives
Intensive chest physiotherapy could decrease extubation failure in mechanically ventilated patients in the ICU.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Landseed Hospital ethics institutional research committee, 24/10/2014, ref: 14-027-B1

## Study design
Single-centre prospective non-randomised study with retrospective case-note review

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Patients requiring mechanical ventilation

## Interventions
Two groups of participants take part in this study.

Control group: Patients who previously received standard nursing care have their case notes from 2015 reviewed for extubation outcomes, mortality, hosptial transfers and clinic data (such as clinical diagnosis, Glasgow coma score, heart rate, blood pressure, respiratory rate, tidal volume,RSBI, length of stay, duration of mechanical ventilation and secretion volume). The results of this are then compared to the intervention group.

Intervention group: Participants take part in a a chest physiotherapy program, which consists of inspiratory muscle training, manual hyperinflation, chest wall mobilization, rib-cage compression, posture drainage, secretion removal, cough function training, extremity range of motion exercise.
Rib cage compression consists of producing mechanical force transferred through the chest wall into the airways during the expiratory phase for the purpose of increasing and redirecting air flow, for pulmonary re-expansion and airway clearance.

Manual hyperinflation was performed using a manual hyperinflation device with inspiratory pressure 40 cm H2O and FIO2 at 0.6, inducing a tidal volume increase and generating subsequent improvement in pulmonary compliance, inspiratory flow, and bronchial secretion clearance.
During implementation of the techniques, SpO2 , heart rate, breathing frequency, and mean arterial pressure were monitored to control the effects while the protocol was performed.
Early mobilization were also given by the physiotherapist according to patients' conditions, vital signs, and clinical performance. These exercises started with sitting on the edge of the bed for moving their limbs, training for standing on their own, and moving off the bed to sit in a chair.
Treatment takes place in 30-40 minute sessions once a day, five times a week, and treatments were given until the patient was discharged from the ICU.
Extubation outcomes are determined according to observations by the attending physician.

### Intervention Type
Other

### Primary outcome measure
Extubation outcomes are determined by the attending physician observations (taken from medical records for control participants):
1. Extubation failure rate, defiened as the need for reintubation within 72 hours after extubation
2. Extubation rate, is calculated as extubation failure participants divided by all participants

### Secondary outcome measures
Rapid Shallow Breathing Index is measured using a handheld spirometer attached to the endotracheal tube while the patient breathes room air for one minute without any ventilator assistance in the intervention group, and taken from medical records for control participants.

### Overall study start date
24/10/2014

### Completion date
24/10/2015

## Eligibility

### Key inclusion criteria
1. Aged 18 years and over
2. Admitted to the Landseed Hospital Intensive Care Unit
3. Require mechanical ventilation for at least 48 hours

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex

Both

### Target number of participants
A total of 437 patients

### Total final enrolment
439

### Key exclusion criteria
1. Brain death patients
2. Ventilator-dependent patients
3. Tracheostomy patients
4. Patients receiving hospice care
5. Patients that have transferred during treatment

### Date of first enrolment
24/10/2014

### Date of final enrolment
24/10/2015

## Locations

### Countries of recruitment
Taiwan

### Study participating centre
**Landseed Hospital**
Departments of Critical Care Medicine
No. 77, Guangtai Road
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## Sponsor information

### Organisation
Landseed Hospital

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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/006arvw77

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Landseed Hospital

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
Taiwan

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

### Intention to publish date
30/09/2016

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | results | 01/11/2018 | 04/01/2021 | Yes | No |