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Correlation between peripheral muscle strength and breathing tube removal outcome

Submission date 01/05/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2019	**Overall study status** Completed	
Last Edited 10/08/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Peripheral muscle weakness is common in critically ill patients with mechanical ventilator. Evidence from previous studies showed that peripheral muscle strength is associated with weaning outcome. However, the predictive value of peripheral muscle strength on extubation outcome from mechanical ventilation has not been investigated. The purpose of this study was to evaluate the relationship between peripheral muscle strength and extubation failure among patients in an intensive care unit (ICU).

Who can participate?
ICU patients who are mechanically ventilated for more than 48 hrs and planning to wean according to standard protocol can participate.

What does the study involve?
Evaluation of the patient's biceps and quadriceps muscle strength

What are the possible benefits and risks of participating?
Benefits: We use peripheral muscle strength to predict patient extubation outcome. It might help the patient to decrease the extubation failure rate.
Risks: Maybe when the patient performs maximum isometric contraction, the blood pressure will increase. However, if the patient can not tolerate the test, we will stop the test and keep follow the patient's vital sign until stable

Where is the study run from?
Landseed International Hospital, Taoyuan City, Taiwan

When is the study starting and how long is it expected to run for?
July 2019 to June 2020

Who is funding the study?
Landseed International Hospital, Taiwan

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Peripheral muscle strength at the time of extubation may be a valuable predictor for extubation outcome

Study objectives
Peripheral muscle strength at the time of extubation may be a valuable predictor for extubation outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2019, Landseed International Hospital ethics institutional research committee (Pingzhen District Taoyuan City Guangtai Road 77, Taiwan), ref: IRB-19-017

Study design
Prospective observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Mechanical ventilation

Interventions
ICU patients who were mechanically ventilated for more than 48 hrs and were planning to wean according to standard protocol were enrolled in this study. Limb muscle strength was assessed using the hand-held dynamometer (MicroFET) on the day of planned extubation.

The MicroFET (Fet stands for Force Evaluating & Testing) is an electronic hand-held dynamometer which fits perfectly in the palm of the hand. It is the most cost effective and ergonomically designed hand-held dynamometer which is available on the market. It was designed to be a standalone gauge for capturing individual force measurements for any muscle test.

For testing isometric quadriceps femoris muscle force, the patient was placed in semi-Fowler position with knee extension and the transducer was placed on the anterior surface of the lower leg proximal to the ankle.
For testing isometric biceps muscle force, the patient was placed in semi-Fowler position with elbow slight flexion and the transducer was placed on the anterior surface of the wrist. Examiners demonstrated and verbally explained the task before testing. Instruction and encouragement were given to have the patient gradually apply maximum force against the transducer pad of the microFET2 over three seconds. At least three repetitions were performed until results were reproducible.

Follow-up continued until the patient was transferred to the general ward.

Intervention Type
Other

Primary outcome(s)
1. Limb muscle strength assessed using the hand-held dynamometer (MicroFET) on the day of planned extubation.
2. Extubation failure rate, defined as the need for reintubation within 72 hours after extubation (determined by the attending physician observation)
3. Extubation rate (calculated as extubation failure participants divided by all participants)

Key secondary outcome(s))
1. In-hospital mortality defined as death occurring during the hospital stay

Completion date
30/06/2020

Eligibility

Key inclusion criteria
ICU patients who were mechanically ventilated for more than 48 hrs and were planning to wean according to standard protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Brain death
2. Ventilator dependent
3. Tracheostomy
4. Patients unable to perform the test were excluded (any rheumatologic conditions, previously known abnormal limitations of strength, amputations, muscular disease)

Date of first enrolment
01/07/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Taiwan

Study participating centre
Landseed International Hospital
Departments of Critical Care Medicine
No. 77 Guangtai Road
Pingzhen District
Taoyuan City

Taiwan
32449

Sponsor information

Organisation
Landseed International Hospital

ROR
https://ror.org/006arvw77

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Landseed International Hospital

Results and Publications

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/08/2021	10/08/2021	Yes	No