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Can serial changes in diaphragm function during the spontaneous breathing trial predict the weaning outcome?

Submission date
31/10/2016

Recruitment status
No longer recruiting

Registration date
03/11/2016

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Other

[_] 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
Mechanical ventilation is where a machine (ventilator) is used to assist or replace a patient's breathing. Weaning from mechanical ventilation is the process of reducing breathing support until the patient can breathe on their own. About 20% of patients have difficulties in weaning from mechanical ventilation. The outcome can be affected by a variety of factors such as heart problems, muscle weakness, and disturbances in blood electrolyte (mineral) levels. As a result, a single factor is not enough to make an accurate prediction. The diaphragm is the main muscle involved in the process of breathing. Diaphragm excursion (movement) and thickening can be measured using ultrasound scans. They have been found to reflect the functioning of the diaphragm and can be used to predict weaning outcome. They are usually measured at the start of a spontaneous breathing trial (SBT), which assesses the patient's ability to breathe while receiving minimal or no ventilator support. There have been no studies on the impact of changes in diaphragm excursion and thickening during the SBT on weaning outcomes. The aim of this study is to find out whether diaphragm function measured using ultrasound during the SBT can be used to predict the weaning outcome.

Who can participate?
Patients aged 18 or over who are have been mechanically ventilated for more than 48 hours

What does the study involve?
When the participants are ready, they undergo an SBT for 2 hours. If the SBT fails, the participant continues with mechanical ventilation. Participants who pass the SBT are extubated (the breathing tube is removed). Diaphragm excursion and thickening are measured by ultrasound at 5 minutes, 30 minutes, 1 hour and 2 hours after the start of the SBT. Blood tests are carried out, heart function is assessed with an ultrasound scan, and the patient's ability to cough is tested.

What are the possible benefits and risks of participating?
Patients who participate in this study are examined and treated by experienced doctors. This study will not cause harm to the patient and will not have a negative impact on the patient's treatment.

Where is the study run from?
Sir Run Run Shaw Hospital (China)

When is the study starting and how long is it expected to run for?
November 2016 to December 2017

Who is funding the study?
Sir Run Run Shaw Hospital (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1628

Study information

Scientific Title
The predictive value of serial changes in diaphragm function during the spontaneous breathing trial for weaning outcome

Study objectives
Diaphragm function measured serially by ultrasound during the spontaneous breathing trial (SBT) is a good predictor of weaning outcome for ICU patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics board of Sir Run Run Shaw Hospital affiliated to Zhejiang University Medical College, 31/10/2016, ref: 20161031-2

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
The tube compensation mode (TC) is used to perform the spontaneous breathing trial (SBT) with the compensation ratio at 85%. The patients undergo SBT for 2 hours in a semi-recumbent position. If the patient fails to tolerant the SBT, the trial is terminated immediately and the patient is returned to the control mode. Patients who pass the 2-hour SBT are extubated. During the SBT, right diaphragm excursion and thickening fraction are evaluated by ultrasonography. Images are obtained at 5 minutes, 30 minutes, one hour and two hours after the initiation of SBT. Rapid shallow breathing index (RSBI) is simultaneously calculated at the bedside.

Laboratory measurements including blood gas, proBNP, chemistry profile, blood count and C reactive protein are obtained and recorded. Cardiac function is assessed by pro-BNP and echocardiography findings such as left ventricular ejection fraction (LVEF), E-point to septal separation (EPSS) and diastolic function. Attending physicians also assess the amount of endotracheal secretion and the patient’s ability to cough, and they are blinded to ultrasound

measurements. According to the weaning outcome, subjects are divided into two groups, the successful group and the failure group.

Diaphragm ultrasound: Patients are measured in a semi-recumbent position with the head of bed elevated between 20° and 40°. The right diaphragmatic excursion is measured with a 3.5-5MHz ultrasound probe (Mindray M9, China). The probe is placed below the right costal margin along the mid-clavicular line. The liver is used as an acoustic window. Firstly, B-mode is used to get the best approach and to select the exploration line. Then M-mode is used to display the motion of the diaphragm along the selected line. The right diaphragm thickness is measured by a 7-10MHz linear ultrasound probe set to B mode placed perpendicularly to the chest wall, in the 8th or 9th intercostal spaces, between the anterior axillary and the midaxillary lines. The diaphragm is imaged at the zone of apposition as three layer structure, including two parallel echoic lines (the diaphragmatic pleura and the peritoneal membrane) and a hypoechoic structure between them (the muscle itself) . On frozen B-mode image, the distance from the middle of the pleural line to the middle of the peritoneal line is the diaphragm thickness. Diaphragm thickening fraction (DTF) = (Thickness at end inspiration – Thickness at end expiration)/Thickness at end expiration.

Intervention Type
Procedure/Surgery

Primary outcome measure
Successful weaning, defined as spontaneous breathing (SB) for >48 hours following extubation without any level of ventilator support. A failed weaning was defined as either SBT failure or the inability to maintain SB for at least 48 hours after extubation.

Secondary outcome measures
N/A

Overall study start date
01/11/2016

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. All patients in the ICU who are mechanically ventilated for more than 48 hours through an endotracheal tube
2. Absence of fever
3. Alert and cooperative
4. Hemodynamically stabile without vasopressors
5. Improved respiratory function with $FiO_2 < 0.5$, PEEP ≤5 cmH_2O, $PaO_2/FiO_2 > 200$ and respiratory rate <30 breaths per minute
6. Aged 18 or over

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. History of diaphragm paralysis
2. Cervical spine injury
3. Neuromuscular diseases
4. A current thoracostomy
5. Pneumothorax
6. Pneumomediastinum

Date of first enrolment
01/11/2016

Date of final enrolment
15/11/2017

Locations

Countries of recruitment
China

Study participating centre
Sir Run Run Shaw Hospital
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Sponsor information

Organisation
Sir Run Run Shaw Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sir Run Run Shaw Hospital

Results and Publications

Publication and dissemination plan
It is the trialist's intention to publish the protocol in November 2016 and the results in December 2017.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Pengmin Zhou
(pmzhou@126.com) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/06/2017	27/11/2020	Yes	No