

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

<b>Submission date</b> 31/10/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/11/2020	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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?

Miss Pengmin Zhou

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## Contact information

**Type(s)**

Scientific

**Contact name**

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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 tolerate 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 stable without vasopressors
5. Improved respiratory function with  $\text{FiO}_2 < 0.5$ ,  $\text{PEEP} \leq 5 \text{ cmH}_2\text{O}$ ,  $\text{PaO}_2/\text{FiO}_2 > 200$  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

China

310016

## **Sponsor information**

**Organisation**

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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?
<a href="#">Protocol article</a>	protocol	23/06/2017	27/11/2020	Yes	No