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# Effect of two different ventilator weaning modes on patients with difficulty weaning

**Submission date**
05/08/2022

**Recruitment status**
No longer recruiting

**Registration date**
14/08/2022

**Overall study status**
Completed

**Last Edited**
11/08/2022

**Condition category**
Respiratory

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Mechanical ventilation (breathing support) is the most commonly used life support technology for critically ill patients. Early ventilator weaning (removal of breathing support) can reduce the risk of ventilator-associated pneumonia and upper respiratory tract injury. It is very important to determine the time of weaning and extubation. Failure to wean and extubate increases related complications and hospitalization costs, prolongs mechanical ventilation time and ICU hospitalization time, and even increases the risk of death. Even if the weaning standard is reached and the spontaneous breathing test (SBT) is successfully carried out, 10-20% of the planned extubation cases fail. Difficult and delayed weaning is one of the reasons for the extension of clinical mechanical ventilation time.
Proportional assisted ventilation (PAV+) is a relatively new ventilation mode, which aims to adapt to patients' changing ventilation needs and respiratory mechanics. Previous studies have shown that compared with the traditional mode, PAV+ is simple to operate, can also improve the sleep quality of critically ill patients and promote the withdrawal of breathing support. However, there are few studies on the physiology of weaning patients with difficult weaning using PAV+ and its impact on the prognosis of patients. The aim of this study is to analyze the effectiveness of PAV+ mode as a method of weaning on patients with difficult/delayed weaning, as well as its impact on diaphragm function.

Who can participate?
Patients aged 18 years and over with difficult weaning or delayed weaning mechanical ventilation.

What does the study involve?
Participants are randomly divided into the experimental group (PAV+ group) and the control group (pressure support ventilation [PSV] group). The participants in the experimental group (PAV+) will be ventilated in PAV+ mode and PAV+ is used for a spontaneous breathing test. The participants in the control group (PSV) will be ventilated in PSV mode and PSV mode is used for a spontaneous breathing test.

What are the possible benefits and risks of participating?
PAV+ mode may be beneficial for weaning in patients with difficult/delayed weaning, and the

treatment method involved in this study is mechanical ventilation. Ventilator-related lung injury and diaphragm injury may occur during mechanical ventilation. The two treatment modes in this study are commonly used in clinic, so this study does not increase the risk. In case of any related damage during the study, the study will provide timely treatment to the participants.

Where is the study run from?
Sir Run Run Shaw Hospital affiliated to Medical College of Zhejiang University (China)

When is the study starting and how long is it expected to run for?
July 2022 to December 2024

Who is funding the study?
Medtronic (China)

Who is the main contact?
1. Kailiang Duan
2. Wenyao Fang

# Contact information

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Public

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
2022-541-01

# Study information

### Scientific Title
Effectiveness of proportional assisted ventilation mode as a method of weaning on patients with difficult weaning

### Study objectives
The purpose of this study is to analyze the effect of the proportional assisted ventilation (PAV+) mode on weaning outcomes in patients with difficult/delayed weaning. The changes in respiratory mechanics in patients with weaning difficulty are compared between PAV+ and pressure support ventilation (PSV) mode.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 19/07/2022, ethics committee of Shaw Hospital Affiliated to Zhejiang University (3 Qingchun East Road, Jianggan District, Hangzhou, China; +86 (0)571 86960497; yyc261@foxmail.com), ref: 310016

### Study design
Randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

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

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

## Interventions
Participants are randomly divided using a random number table into the experimental group (PAV+ group) and the control group (PSV group). The participants in the experimental group (PAV+) will be ventilated in PAV+ mode and use PAV+ for a spontaneous breathing test. The participants in the control group (PSV) will be ventilated in PSV mode and use PSV mode for a spontaneous breathing test.

The PAV+ group will be set to PAV+ mode and the support level will be adjusted to meet the patients' ventilation needs. Using PAV+ for a spontaneous breathing test, the definition of success is that the subject can tolerate 25% support. If the patient does not tolerate PAV+ mode, they are changed to pressure-controlled ventilation (PCV) assist-control (A/C) mode support. The PSV group will be set as PSV mode respiratory support, and the support level will be adjusted to meet patients' ventilation needs. PSV is used for a spontaneous breathing test (PSV 5 cmh2o+peep 5 cmh2o). If the patient does not tolerate PSV mode, they are changed to PCV-A/C mode support.

When the patient reaches the weaning criteria (when the condition is stable), they start weaning for half an hour per day using one of the two weaning modes. Patients are only observed during hospitalization and no follow-up will be needed.

## Intervention Type
Device

## Phase
Not Applicable

## Primary outcome measure
1. Diaphragm activity and thickening fraction evaluated by phrenic ultrasound every morning when weaning
2. Ventilator parameters and gas exchange indicators (Peak Inspiratory Pressure [PIP], positive end-expiratory pressure [PEEP], work of breathing [WOB], $FiO_2$, mechanical energy [MP] , maximal inspiratory pressure [MIP], rapid shallow breathing index [RSBI], pH, $PaCO_2$, $ETCO_2$, PaO2/$FiO_2$, etc) directly observed on the ventilator data acquisition system every day when weaning
3. First spontaneous breathing test (SBT) time, first SBT success time and extubation success time directly recorded after grouping according to the actual situation of each patient

## Secondary outcome measures
Obtained from the patient's medical records at discharge:
1. No ventilator-free day (VFD) within 28 days
2. Length of stay in ICU
3. ICU mortality
4. Hospitalization mortality
5. Complications after extubation
6. Success rate and time of 28-day machine removal

### Overall study start date
01/07/2022

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
1. Age ≥18 years old
2. Patients with mechanical ventilation ≥48 h
3. Patients with mechanical ventilation who meet the first SBT failure (excluding iatrogenic factors)
4. Volunteer to participate in this study and sign the informed consent form. If the subject is unable to read and sign the informed consent form due to incapacity and other reasons, or the subject is a minor, his guardian is required to represent the informed process and sign the informed consent form. If the subject is unable to read the informed consent form (e.g. illiterate subjects), the witness is required to witness the informed process and sign the informed consent form

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
256

### Key exclusion criteria
1. Myasthenia gravis and other neuromuscular diseases
2. Tracheoesophageal fistula, tracheomediastinal fistula
3. Patients with high endogenous peep

### Date of first enrolment
02/09/2022

### Date of final enrolment
30/11/2024

## Locations

### Countries of recruitment

China

**Study participating centre**
**Sir Run Run Shaw Hospital affiliated to Medical College of ZheJiang University**
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# Sponsor information

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Medtronic (China)

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**Sponsor type**
Industry

**Website**
http://www.medtronic.com/cn-zh/index.html

**ROR**
https://ror.org/02m7bcm44

# Funder(s)

**Funder type**
Industry

**Funder Name**

Medtronic

**Alternative Name(s)**
Medtronic Inc.

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
United States of America

# Results and Publications

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

**Intention to publish date**
31/12/2025

**Individual participant data (IPD) sharing plan**
All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**
Published as a supplement to the results publication