

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

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<b>Registration date</b> 14/08/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/01/2026	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 and lung ventilation function.

### Who can participate?

Patients aged 18 years, Failed SBT (Spontaneous Breathing Trial) plus mechanical ventilation duration  $\geq$  48 hours; or successful SBT plus mechanical ventilation duration  $\geq$  7 days.

### 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 2026

Who is funding the study?

Medtronic (China)

Who is the main contact?

1.Huiqing Ge

2.Siyu Zhang

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

2022-541-04

## Study information

### Scientific Title

Effectiveness of proportional assisted ventilation mode as a method of weaning on patients with difficult and delayed weaning

### Study objectives

Current study objectives as of 11/09/2025:

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, and to compare the changes in respiratory mechanics, Electrical Impedance Tomography (EIT) parameters, and diaphragmatic ultrasound indices among these patients under the PAV+ mode and the pressure support ventilation (PSV) mode.

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### Previous 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

Ethics approval required

### Ethics approval(s)

approved 14/08/2022, Ethics Committee of Sir Run Run Shaw Hospital (Sir Run Run Shaw Hospital affiliated to Medical College of Zhejiang University 3 Qingchun East Road Shangcheng District, Hangzhou, 310016, China; +86 571 86006811; 594961420@qq.com), ref: 2022-541-04

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

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Patients requiring invasive mechanical ventilation

## Interventions

Current interventions as of 16/01/2026:

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 cmh<sub>2</sub>o+peep 5 cmh<sub>2</sub>o). 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 observed during hospitalization and follow-up will be needed.

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Previous 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 cmh<sub>2</sub>o+peep 5 cmh<sub>2</sub>o). 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

### **Drug/device/biological/vaccine name(s)**

PB840 ventilator

### **Primary outcome(s)**

Current primary outcome(s) as of 16/01/2026:

Obtained from the patient's medical records at discharge:

1. Successful weaning rate
2. Ventilator-free days within 28 days
3. Time from enrollment to successful weaning
4. Total duration of mechanical ventilation
5. Total length of hospital stay and ICU length of stay
6. Reintubation rate within 28 days after enrollment

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Previous primary outcome measure as of 11/09/2025:

1. Before and after randomization, the patients' diaphragmatic function and pulmonary function are evaluated using diaphragmatic ultrasound or Electrical Impedance Tomography (EIT) at regular intervals, respectively.
2. During the weaning period, ventilator parameters and gas exchange indicators are directly monitored via the ventilator data acquisition system on a daily basis, including peak inspiratory pressure (PIP), positive end-expiratory pressure (PEEP), work of breathing (WOB), fraction of inspired oxygen (FiO<sub>2</sub>), mechanical power (MP), maximal inspiratory pressure (MIP), rapid shallow breathing index (RSBI), pH value, arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>), end-tidal partial pressure of carbon dioxide (ETCO<sub>2</sub>), and PaO<sub>2</sub>/FiO<sub>2</sub> ratio (oxygenation index), etc.
3. After grouping, outcome indicators such as the time of successful extubation are directly recorded according to the actual condition of each patient.

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Previous 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<sub>2</sub>, mechanical energy [MP], maximal inspiratory pressure [MIP], rapid shallow breathing index [RSBI], pH, PaCO<sub>2</sub>, ETCO<sub>2</sub>, PaO<sub>2</sub>/FiO<sub>2</sub>, 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

### **Key secondary outcome(s)**

Current key secondary outcome(s) as of 16/01/2026:

Diaphragm function will be assessed using diaphragm ultrasound and electrical impedance tomography (EIT) at two time points, before and after randomization. During the weaning process, ventilator parameters and gas exchange indices will be monitored daily.

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Previous secondary outcome measures as of 11/09/2025:

Obtained from the patient's medical records at discharge:

1. Successful Weaning
2. ICU Length of Stay
3. Time from Enrollment to Successful Weaning
4. Total Duration of Mechanical Ventilation
5. Duration of Mechanical Ventilation within 28 Days of Enrollment
6. Total Hospital Length of Stay
7. Reintubation within 28 Days of Enrollment

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Previous 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

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 11/09/2025:

1. Age  $\geq 18$  years old
2. Patients with mechanical ventilation  $\geq 48$  h
3. Failed SBT (Spontaneous Breathing Trial) mechanical ventilation duration  $\geq 48$  hours; or successful SBT plus mechanical ventilation duration  $\geq 7$  days.

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

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Previous inclusion criteria:

1. Age  $\geq 18$  years old
2. Patients with mechanical ventilation  $\geq 48$  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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

90 years

**Sex**

All

**Total final enrolment**

250

**Key exclusion criteria**

Current key exclusion criteria as of 16/01/2026:

1. Airway/Pleural pathology: Pneumothorax, bronchopleural or bronchotracheal fistula
2. Concomitant neuromuscular disease
3. Severe chronic obstructive pulmonary disease

4. Contraindications to EIT (e.g., chest wall wounds or implanted pacemakers)
5. Other: Advanced malignancy (Stage IV) or withdrawal/discontinuation of treatment before extubation

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Previous exclusion criteria as of 11/09/2025:

1. Neuromuscular diseases (e.g., myasthenia gravis)
2. Tracheoesophageal fistula, tracheomediastinal fistula, etc.

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Previous 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**

31/12/2026

## **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**

**Organisation**

Medtronic (China)

**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

## 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