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

Submission date 05/08/2022	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/08/2022	**Overall study status** Ongoing	
Last Edited 16/01/2026	**Condition category** Respiratory	

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 ≥ 48 hours; or successful SBT plus mechanical ventilation duration ≥ 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
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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
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 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 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 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

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

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_2), mechanical power (MP), maximal inspiratory pressure (MIP), rapid shallow breathing index (RSBI), pH value, arterial partial pressure of carbon dioxide ($PaCO_2$), end-tidal partial pressure of carbon dioxide ($ETCO_2$), and PaO_2/FiO_2 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.

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_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

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.

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

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 ≥18 years old
2. Patients with mechanical ventilation ≥48 h
3. Failed SBT (Spontaneous Breathing Trial) mechanical ventilation duration ≥ 48 hours; or successful SBT plus mechanical ventilation duration ≥ 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 ≥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

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
3 QingChun East Road
Jianggan District
HangZhou
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310016

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes