Dynamic diaphragm function trajectory via ultrasound predicts weaning outcomes in mechanically ventilated patients

Submission date 10/03/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [ ] Protocol
Registration date 11/03/2026	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 10/03/2026	**Condition category** Respiratory	[ ] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Mechanical ventilation (MV) is a lifesaving intervention for critically ill patients with respiratory failure. However, the process of liberating patients from the ventilator, known as weaning, remains a significant clinical challenge. Approximately 20-30% of patients experience weaning failure, which is associated with dramatically increased morbidity, mortality, and healthcare costs. Prolonged ventilation can lead to complications such as ventilator-associated pneumonia, diaphragm dysfunction, and ICU-acquired weakness.

Traditional weaning predictors (e.g., rapid shallow breathing index) and clinical parameters often lack sufficient sensitivity and specificity. Recent evidence highlights the critical role of the diaphragm. Ventilator-induced diaphragmatic dysfunction (VIDD) can develop within hours of controlled ventilation and is a key contributor to weaning failure. Bedpoint ultrasonography has emerged as a non-invasive, real-time tool to assess diaphragmatic structure and function through metrics like diaphragmatic thickness, thickening fraction (DTF), and mobility. However, most studies provide only single or intermittent "snapshots" of diaphragmatic function. The dynamic trajectory of these ultrasound parameters over the course of mechanical ventilation—how they change from initiation, through support, to weaning trials—is poorly characterized but may hold superior prognostic value for weaning outcomes. A detailed understanding of this trajectory could enable earlier identification of patients at risk for diaphragm dysfunction and weaning failure, allowing for timely, personalized interventions such as adjusted ventilator settings, targeted physiotherapy, or pharmacological support.

The Diaphragm-Protective Ventilation (DMV) study is a single-center, prospective cohort study designed to address this knowledge gap. Its primary objective is to establish and validate the predictive value of the longitudinal trajectory of ultrasound-assessed diaphragmatic function for weaning outcomes in critically ill, mechanically ventilated patients. The findings are intended to provide evidence for the early identification of diaphragmatic dysfunction and the optimization of weaning strategies in clinical practice.

Who can participate?
Adult patients aged 18 years old and over receiving invasive mechanical ventilation in the Intensive Care Unit (ICU).

What does the study involve?
This is a prospective cohort study to dynamically assess diaphragmatic function using bedside ultrasound to predict weaning outcomes in mechanically ventilated patients. During the study, researchers will perform ultrasound examinations every other day to monitor indicators such as diaphragmatic thickness, diaphragmatic thickening fraction, and diaphragmatic mobility.

What are the possible benefits and risks of participating?
Potential Benefits:
Participants will be managed under a refined ventilation strategy informed by dynamic ultrasound assessment of diaphragmatic function to predict weaning prognosis. This approach may help reduce the risk of ventilator-associated injury and potentially increase their chances of successful and earlier liberation from the ventilator.
Participants will receive close respiratory physiological monitoring.
Participant's research data will contribute to improving future respiratory treatment strategies for critically ill patients.
Potential Risks and Discomforts:
As an observational study, the primary risk involves participation in more frequent ultrasound examinations. However, ultrasound is a routine, non-invasive, and radiation-free bedside procedure.

Where is the study run from?
This study is conducted in the Intensive Care Unit (ICU) of The First Affiliated Hospital of Jinan University, China.

When is the study starting and how long is it expected to run for?
March 2026 to January 2030.
Total Study Duration: The entire research project (including recruitment, follow-up, and data analysis) is expected to last approximately 4 years.

Who is funding the study?
The First Affiliated Hospital of Jinan University, China.

Who is the main contact?
Dr. Wan-Jie Gu, guwanjie@jnu.edu.cn.

Contact information

Type(s)
Public, Principal investigator, Scientific

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Study information

Scientific Title
Dynamic diaphragm function trajectory via ultrasound predicts weaning outcomes in mechanically ventilated patients: the diaphragm-protective ventilation (DMV) study

Acronym
Diaphragm-Protective Ventilation (DMV) study

Study objectives
The Diaphragm-Protective Ventilation (DMV) study aim to establish and validate the predictive value of the longitudinal trajectory of ultrasound-assessed diaphragmatic function for weaning outcomes in critically ill, mechanically ventilated patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/10/2025, Scientific Research Ethics Committee of the First Affiliated Hospital of Jinan University (613 Huangpu Avenue West, Guangzhou, 510630, China; +86 133 1883 1222; haiyanyin1867@126.com), ref: KY-2025-265

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Dynamically monitor diaphragmatic function in mechanically ventilated patients in the intensive care unit (ICU) using point-of-care ultrasound, explore its trajectory, and evaluate its predictive value for weaning outcomes.

Interventions
This is a prospective cohort study to dynamically assess diaphragmatic function using bedside ultrasound to predict weaning outcomes in mechanically ventilated patients. During the study, researchers will perform ultrasound examinations every other day to monitor indicators such as your diaphragmatic thickness, diaphragmatic thickening fraction, and diaphragmatic mobility.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Successful extubation measured using data collection on reintubation or tracheostomy at within 48 h after extubation

Key secondary outcome(s))

Completion date

31/01/2030

Eligibility

Key inclusion criteria

1. Age ≥ 18 years old
2. Intubated orally or nasotracheal with invasive mechanical ventilation
3. Expected duration of mechanical ventilation > 48 hours
4. Informed consent was obtained from their legal representatives of patients

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

120 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Previous known diaphragmatic disease or paralysis (e.g., cervical spinal cord injury, amyotrophic lateral sclerosis, etc.)
2. Previous history of thoracic surgery, especially involving the diaphragm or lung resection, may severely affect diaphragmatic anatomy
3. Use of neuromuscular blocking agents
4. History of chronic obstructive pulmonary disease
5. Pregnant women
6. Technical difficulties in surface ultrasound examination (e.g., severe subcutaneous emphysema, extreme obesity)
7. Other conditions considered by the investigator to be inappropriate for inclusion (e.g., terminal state, treatment withdrawal).

Date of first enrolment
30/03/2026

Date of final enrolment
15/01/2030

Locations

Countries of recruitment
China

Sponsor information

Organisation
First Affiliated Hospital of Jinan University

ROR
https://ror.org/05d5vvz89

Funder(s)

Funder type

Funder Name
Jinan University

Alternative Name(s)
JNU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available