

The effect of mistimed mechanical breathing assistance on patient outcomes

Submission date 06/11/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/11/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/11/2020	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Invasive assisted mechanical ventilation (MV) provides primary life support to the patients without the ability to breathe in the intensive care unit (ICU). A mismatch between the MV and the breathing rate controlled by the brain of the patients results in patient-ventilator asynchrony (PVA), which will lead to a series of adverse clinical outcomes. Automatic detection of PVA is highly necessary for monitoring its occurrence in clinic.

Who can participate?

Patients aged above 18 years, admitted to intensive care unit and on invasive mechanical ventilation

What does the study involve?

From enrolment to the end of their participation, we will pay attention to the incidence of patient-ventilator asynchrony during invasive mechanical ventilation and the outcome when they leave ICU. The total duration of observation is the mechanical ventilation time in ICU and the total duration of follow-up are 28 days.

What are the possible benefits and risks of participating?

Improper mechanical respiratory assistance can lead to a series of poor clinical outcomes. Based on the ventilator waveform monitoring, patient-ventilator asynchrony can be further understood on the prognosis of patients, providing a basis for the understanding and treatment of improper mechanical respiratory assistance in clinical practice. Because this is an observational trial we will not consider the risks during our observation.

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?

Nov ember 2019 to November 2020

Who is funding the study?

Sir Run Run Shaw Hospital, school of medicine, Zhejiang University, China

Who is the main contact?

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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

20190916-16

Study information

Scientific Title

The influence of the incidence of patient-ventilator asynchrony on the prognosis of mechanical ventilated patients—analysis based on the deep learning results of ventilator waveforms

Acronym

PVA

Study objectives

Mismatch between the MV and the need of the patients results in patient ventilator asynchrony (PVA), which will lead to a series of adverse clinical outcomes. So our observational trial is to learn more about the effects of the incidence of patient-ventilator asynchrony on the prognosis of invasive mechanical ventilated patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/09/2019, Ethics committee of Sir Run Run Shaw Hospital of Zhejiang University (Zhejiang 310016, China; +86 571 86006811; 594961420@qq.com), ref: 20190916-16

Study design

Cross-sectional cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Patients with invasive mechanical ventilation

Interventions

From enrolment to the end of their participation, we will pay attention to the incidence of patient-ventilator asynchrony during invasive mechanical ventilation and the outcome when they leave ICU. The total duration of observation is the mechanical ventilation time in ICU and the total duration of follow-up are 28 days.

Ventilator waveforms will be collected from the adults (> 18 years old) in the ICUs. Data annotation will be performed on a manually screened dataset rather than on the whole one. A self-developed software is used for annotating the waveforms in the screened dataset. We propose a 2-layer long short-term memory (LSTM) network to detect two common types of PVA – double triggering (DT) and ineffective inspiratory effort during expiration (IEE). The labels of “DT”, “IEE”, and “Others” will be given to each breath.

Intervention Type

Other

Primary outcome(s)

The incidence of PVA during the mechanical ventilation time

Key secondary outcome(s)

Analysis of the related factors of PVA incidence:

1. Practice models and patterns of mechanical ventilation in patients during the mechanical ventilation time
2. Mechanical ventilation time
3. Mortality at 28 days

Completion date

15/11/2020

Eligibility**Key inclusion criteria**

1. Age above 18 years
2. Admitted to the intensive care unit and on invasive mechanical ventilation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

15/11/2019

Date of final enrolment

15/11/2020

Locations**Countries of recruitment**

China

Study participating centre

Sir Run Run Shaw Hospital affiliated to medical college of ZheJiang University

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HangZhou

China

310000

Sponsor information

Organisation

Sir Run Run Shaw Hospital, school of medicine, Zhejiang university

ROR

<https://ror.org/00ka6rp58>

Funder(s)

Funder type

University/education

Funder Name

Sir Run Run Shaw Hospital, school of medicine, Zhejiang university

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2020	05/11/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes