

# The effect of mistimed mechanical breathing assistance on patient outcomes

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

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

## Secondary study design

Cross sectional study

## Study setting(s)

Hospital

## Study type(s)

Other

## Participant information sheet

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

## 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 measure**

The incidence of PVA during the mechanical ventilation time

**Secondary outcome measures**

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

**Overall study start date**

02/09/2019

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

at least 300

**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

3 QingChun East Road

Jiangan district

HangZhou

China

310000

## **Sponsor information**

**Organisation**

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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**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

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

15/11/2021

**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?
<a href="#">Results article</a>	results	01/05/2020	05/11/2020	Yes	No