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The effect of mistimed mechanical breathing assistance on patient outcomes

Submission date
06/11/2019

Recruitment status
No longer recruiting

Registration date
12/11/2019

Overall study status
Completed

Last Edited
05/11/2020

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 trialwe 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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Scientific

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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
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Sponsor information

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

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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?
Results article	results	01/05/2020	05/11/2020	Yes	No