

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of implementing a management protocol of patient-ventilator asynchrony on the clinical outcomes of patients admitted to ICU

Protocol summary

Study aim

Determining the impact of the implementation of the management protocol of inconsistency between the patient and the ventilator on the clinical outcomes of patients admitted to the ICU

Design

A clinical trial with a control group with parallel, one-sided blind, randomized groups on 60 patients was used for randomization using the random permutation block method, spss software

Settings and conduct

This study is a randomized clinical trial and is conducted in the Mega ICU1 department of Golestan Ahvaz Hospital. The sample size is 60 people who will be divided into two intervention and control groups by random number table. The study is one-sided blind

Participants/Inclusion and exclusion criteria

- Age range between 15 and 65 years
- Patients who are under mechanical ventilation with a ventilator.
- No more than 3 days have passed since the patient was admitted to the ICU.
- Informed consent from the legal guardian for the patient's participation in the study
- Apache 2 score between 30 and 50
- Having a spontaneous breathing effort in addition to the forced breaths of the ventilator (the patient is on assisted-controlled or spontaneous modes)

Intervention groups

Patients are divided into two groups, an intervention group and a control group. In the intervention group, the protocol is executed for 60 seconds until the lack of synchronization between the patient and the device is resolved. This cycle continues. The control group received routine care

Main outcome variables

The duration of connection to the ventilator, asynchrony between the patient and the device, the rate of death of the patient, spontaneous extubation of the patient

General information

Reason for update

Acronym

PVA

IRCT registration information

IRCT registration number: **IRCT20231001059572N1**

Registration date: **2023-12-08, 1402/09/17**

Registration timing: **prospective**

Last update: **2023-12-08, 1402/09/17**

Update count: **0**

Registration date

2023-12-08, 1402/09/17

Registrant information

Name

Maryam Roozehavazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3375 4852

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2025-02-28, 1403/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of implementing a management protocol of patient-ventilator asynchrony on the clinical outcomes of patients admitted to ICU
Public title	pva review
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Connecting to the ventilator Do not be under ventilator for more than three days Apache score between 30 and 50 Having the informed consent of the patient's guardian Age range from 15 to 65 years Having a spontaneous breathing effort in addition to the forced breathing of the ventilator
Exclusion criteria:	Receiving neuromuscular blocking drugs during the study Creating conditions that cause the patient to be on the controlled modes of the ventilator for a long time (such as brain death)
Age	From 15 years old to 65 years old
Gender	Both
Phase	N/A
Groups that have been masked	<i>No information</i>
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	This study is a randomized clinical trial in two intervention and control groups. The sample size was determined based on the findings of previous studies with the help of the med calc statistical software with a power of 90% and an error of 10%, 60 cases (30 people in each group). Due to the possibility of sample dropout, 10% will be added to the above sample size. First, the samples will be selected according to the available sampling method according to the entry criteria, and then using the replacement block randomization method in the two intervention groups. and control (33 people each) will be randomly assigned. In this way, 11 blocks of 6 will be selected and then one of the 6 combinations of two groups will be assigned in each block
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Golestan St., Jundishapur University of Medical Sciences, Ahvaz, Faculty of Nursing and Midwifery

City

ahvaz

Province

Khouzestan

Postal code

۶۱۵۴۸۷۸۴۲۵

Approval date

2023-12-07, 1402/09/16

Ethics committee reference number

1402.472

Health conditions studied

1

Description of health condition studied

Patients who need to be connected to a ventilator due to breathing problems or other problems

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The duration of dependence on the ventilator

Timepoint

The number of days dependent on the ventilator

Method of measurement

check list

Secondary outcomes

1

Description

Length of hospitalization in the special ward

Timepoint

The number of days of hospitalization in the special ward

Method of measurement

check list

Intervention groups

1

Description

In the intervention group, the researcher checked the mechanical ventilation status of the patients twice a day during the morning and evening shifts using the patient asynchrony management protocol and the ventilator device and, if necessary, took the necessary care and treatment based on the PVA management protocol and in coordination He will do for the patient with the ICU specialist doctor and the nurses in the ward. The control group will receive routine ward care. In the control group, the routine care of the patients is received by the relevant personnel, and the protocol was not taught to the nurse

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mohammad Adinae

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Golestan - Farvardin St. - Golestan Educational and Medical Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Jundishapur University of Medical Sciences, Ahvaz,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

maryam rozeahvazy

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Senior students

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Golestan, Isfahan Street, between Bahman and Esfand, Isfahan Complex, Unit 7

City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable