

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Clinical trial of the effect of melatonin administration on duration of mechanical ventilation in patients requiring hospitalization in the intensive care unit

Protocol summary

Study aim

The effect of melatonin administration on duration of mechanical ventilation in patients requiring hospitalization in the intensive care unit of Golestan hospital, Ahvaz

Design

This study will be a randomized double-blind controlled clinical trial in 60 patients who will be randomly divided into two groups: medication and control group, in order to examine the effect of prescribing melatonin on the duration of mechanical ventilation in comparison with placebo among ICU patients. The randomisation method will be the use of a random number table and the phase of clinical trial is phase 4.

Settings and conduct

This study will be carried out among 60 patients hospitalized in ICU of Golestan hospital in Ahvaz. After obtaining written consent form, the patients will be randomly divided into case group and placebo group by means of table of random numbers. The patients in case group and placebo group will receive 3mg melatonin or the placebo through nasogastric tube every night at 9 P.M. The prescription will be continued until weaning the mechanical ventilation.

Participants/Inclusion and exclusion criteria

The Inclusion criteria: Patients older than 18-year-old who entered the ICU with the reduced GCS and need for mechanical ventilation in first 48-hour hospitalization. The exclusion criteria: liver failure; Kidney failure; Pregnancy; Patients with brain tumor; Patients with GCS<4; The hypersensitivity history of melatonin

Intervention groups

Intervention group: the group that takes melatonin.
Control group : the group that takes placebo.

Main outcome variables

The duration of mechanical ventilation; Ventilator associated pneumonia occurrence; The duration of ICU

stay; Mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170729035360N1**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Mandana Izadpanah

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology Development of the Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of melatonin administration on duration of mechanical ventilation in patients requiring hospitalization in the intensive care unit

Public title
Evaluation of effect of melatonin on the duration of mechanical ventilation in patients requiring hospitalization in the intensive care unit

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
admission in intensive care unit age older than 18 year old need for mechanical ventilation
Exclusion criteria:
Hepatic failure kidney Failure Pregnancy Brain Tumor The hypersensitivity history of melatonin Patients with GCS<4

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, Table of random number will be used for random assignment to intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind study. The patient, the prescribing physician, as well as the nurse, will not be aware of the contents of the coded packaged medication or placebo.

Placebo
Used

Assignment
Parallel

Other design features
In randomization we use a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Golestan boulevard, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

1579461357

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.AJUMS.REC.1396.395

Health conditions studied

1

Description of health condition studied

Dependence on respirator

ICD-10 code

Z99.1

ICD-10 code description

Dependence on respirator

Primary outcomes

1

Description

The duration of mechanical ventilation dependence

Timepoint

daily

Method of measurement

visual

Secondary outcomes

1

Description

mortality

Timepoint

daily

Method of measurement

visual

2

Description

The duration of hospitalization in the intensive care unit

Timepoint

daily

Method of measurement

visual

Intervention groups**1****Description**

Prescription of melatonin, 3 mg daily, in intervention group

Category

Treatment - Drugs

2**Description**

prescription of placebo, daily, in control group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan hospital

Full name of responsible person

Dr Mandana Izadpanah

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Golestan hospital, Golestan Blvd, Ahvaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research and Technology Development of the Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Makhmalzadeh

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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

Deputy of Research and Technology Development of the Ahvaz Jundishapur 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 Jundishapur University of Medical Sciences

Full name of responsible person

Mandana Izadpanah

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

The results of the study will be published in an original article after the study is completed.

When the data will become available and for how long

Access to the article will begin after publishing the article.

To whom data/document is available

Only for researchers working in academic institutions and scientific data will be available.

Under which criteria data/document could be used

The data for this study are available for use in review articles, systematic analyzes.

From where data/document is obtainable

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What processes are involved for a request to access data/document

After sending the email to the responsible author, the request will be answered as soon as possible.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

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