

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the Effects of Melatonin versus Placebo on Amount of Opioids Intake in Patients Admitted to Intensive Care Unit

Protocol summary

Study aim

Evaluation the effects of melatonin versus placebo on amount of opioids intake in patients admitted to intensive care unit.

Design

Randomised, controlled, parallel group trial with blinded outcome assessment. Randomisation was centralised with simple randomization with random number tables

Settings and conduct

Fifty two patients in age group 18 to 80 years admitted to intensive care unit of Ahvaz Golestan hospital are randomly divided by random number tables into control and intervention groups (n=26 cases). Patients, researchers responsible for data collection and analyses are blind to the groups allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria are age range 18 – 65 year and traumatic patients who are admitted to intensive care unit; The exclusion criteria are patients with GCS less than 4, pregnant patients, patients with renal and liver failure, patients with brain tumor and allergic reaction to melatonin.

Intervention groups

In the Intervention group, on arrival at the intensive care unit, the patients will be received melatonin with dose of 3 mg every night until discharge. In the control group, on arrival at the intensive care unit, the patients will be received placebo every night until discharge.

Main outcome variables

The amount of prescribed opioid analgesic medication during hospitalization, duration of hospitalization, the time required for mechanical ventilation and rate of mortality will compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190912044752N1**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Farahmand Kalantari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3337 4303

Email address

kalantari.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effects of Melatonin versus Placebo on Amount of Opioids Intake in Patients Admitted to Intensive Care Unit

Public title

Evaluation the Effects of Melatonin on Amount of Opioids Intake

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 – 80 year Traumatic patients who are admitted to intensive care unit

Exclusion criteria:

Patients with GCS less than 4 Pregnant patients Patients with renal and liver failure Patients with brain tumor Allergic reaction to melatonin

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the intervention or placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, responsible for collecting data and data analyzer are blind to the groups allocation.

Placebo

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

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.AJUMS.REC.1396.949

Health conditions studied

1

Description of health condition studied

Traumatic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of prescribed opioid analgesic medication

Timepoint

Daily from admission and starting intervention to discharge

Method of measurement

Total receiving dose of opioid analgesic medication

2

Description

Duration of hospitalization

Timepoint

Duration of admission to discharge

Method of measurement

Checklist

3

Description

The time required for mechanical ventilation

Timepoint

Duration of hospitalization

Method of measurement

Checklist

4

Description

Rate of mortality

Timepoint

Duration of hospitalization

Method of measurement

The number of patients who died

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On arrival at the intensive care unit, the patients will be received melatonin with dose of 3 mg every night until discharge.

Category

Treatment - Drugs

2

Description

Control group: On arrival at the intensive care unit, the patients will be received placebo every night until discharge.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Farhad Soltani

Street address

Golestan Hospital, Farvardin Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3374 3037

Email

soltani-f@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8383

Email

info@ajums.ac.ir

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

Farahmand Kalantari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Golestan Hospital, Farvardin Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3374 3037

Email

farahmandbm@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Farhad Soltani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Golestan Hospital, Farvardin Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3374 3037

Email

soltani-f@ajums.ac.ir

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

Ahvaz University of Medical Sciences

Full name of responsible person

Farahmand Kalantari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Golestan Hospital, Farvardin Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3374 3037

Email

farahmandbm@gmail.com

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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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