

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 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

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##### 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.

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##### Province

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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

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**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**

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**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