

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of melatonin in the treatment of delirium in critically ill patients admitted to the intensive care unit

Protocol summary

Study aim

The effect of melatonin in the treatment of delirium in critically ill patients admitted to the intensive care unit of Vali-Asr Hospital in Arak

Design

The study will be double blind and clinical trial. 80 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients diagnosed with delirium in Valiasr hospital in Arak city are divided into 2 groups by simple randomization using block method. The study is double-blind. In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients diagnosed with delirium by DSM-V criteria; Age 18 to 80 years; RASS criterion greater than or equal to 3; lack of primary neurological disease such as stroke, dementia, psychosis; Absence of seizure history; The patient should not be so restless that there is a possibility of harming himself or others and it is not possible to wait for the response of oral medication; Insensitivity to drugs; ; No history of SSRI use
Exclusion criteria: non-consent of companions

Intervention groups

Intervention group 1: Patients in this group will receive 3 mg of melatonin at night for 5 days. Intervention group 2: The patients in this group will receive haloperidol (Caspian Tahind Pharmaceutical Company, Iran) at a dose of 2.5 mg intramuscularly every 6 hours. If necessary, up to 40 mg per day can be prescribed, and if delirium is not controlled with this dose, other drugs are used and the patient is excluded from the study.

Main outcome variables

Sedation; Illness severity; Number of hospitalization days, mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N189**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin in the treatment of delirium in critically ill patients admitted to the intensive care unit

Public title

The effect of melatonin in the treatment of delirium in critically ill patients admitted to the intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients for whom a diagnosis of delirium was made by DSM-criteria were included. Age 18 to 80 years RASS criterion greater than or equal to 3 Absence of primary neurological disease such as stroke, dementia, psychosis Failure to enter patients who are in a coma for more than 24 hours and have a structural reason for their low level of consciousness No history of seizures Absence of underlying disease The patient should not be so restless that there is a possibility of harming herself or others and she cannot wait for the response of oral medication. Absence of pregnancy and breastfeeding Insensitivity to drugs Absence of QTc greater than 440 ms No history of SSRI use

Exclusion criteria:

Lack of consent of the companions (the person in charge of the patient) to receive the medicine and the patient's participation in the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the supervisor knows about the grouping and prescribes the drugs for the patients, and the interns do not know about the prescribed drugs, and the follow-up of the patients is with the interns, and the analyst does not know about the grouping, and as a result, the study will be double-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

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Province

Markazi

Postal code

3848176941

Approval date

2023-07-04, 1402/04/13

Ethics committee reference number

IR.ARAKMU.REC.1402.114

Health conditions studied**1****Description of health condition studied**

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes**1****Description**

Sedation

Timepoint

Daily to 7 days

Method of measurement

Based on the RASS score

2**Description**

Illness severity

Timepoint

Daily to 7 days

Method of measurement

Apachi score

3

Description

Number of hospitalization days

Timepoint

End of study

Method of measurement

File

4

Description

Mortality

Timepoint

End of study

Method of measurement

File

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group will receive 3 mg of melatonin at night for 5 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: The patients in this group will receive haloperidol (Caspian Tahind Pharmaceutical Company, Iran) at a dose of 2.5 mg intramuscularly every 6 hours. If necessary, up to 40 mg per day can be prescribed, and if delirium is not controlled with this dose, other drugs are used and the patient is excluded from the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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