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
Iran (Islamic Republic of)

Phone
+98 86 3222 2003

Email address
f.farokhi@arakmu.ac.ir

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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City
Arak

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
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Davoud Hekmatpou
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
hekmatpou@arakmu.ac.ir
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
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street

City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Behnam Mahmodie
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
mahmodie@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Fatemeh Ghafari
Position
medicine student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
ghafari@yahoo.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