

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of melatonin on positive and negative symptoms of schizophrenic patients admitted to psychiatry ward of Golestan hospital in 2021-2022

Protocol summary

Study aim

Evaluating the effect of melatonin on positive and negative symptoms of schizophrenic patients admitted to psychiatry ward of Golestan hospital in 2021-2022

Design

Clinical trial with case control group, randomized parallel group, blinded designed on 46 patients. randomization list is prepared by a statistician.

Settings and conduct

Schizophrenic patients who will be admitted to the psychiatry ward of Golestan hospital and treated with risperidone divided into 2 groups. In the case group, patients will be treated with risperidone and 6 mg melatonin, in the control group patients will be treated with risperidone and placebo. The psychiatrist, nurse, evaluator student, and patients will not be aware of allocation. All of the measures will be registered by one evaluator. Positive, negative, and general signs of schizophrenia will be evaluated with PANSS scale. A reduction of 20 percent or more in PANSS score, during the study, is considered significant.

Participants/Inclusion and exclusion criteria

schizophrenic patients who have admitted in psychiatry ward, with age 18 to 65 and have treated with only risperidone, without history of drug reaction to melatonin

Intervention groups

In case group, patients will be treated with risperidone and 6 mg melatonin, in control group patients will be treated with risperidone and placebo

Main outcome variables

Positive and negative symptoms; sleep; metabolic syndrome caused by antipsychotic drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210528051416N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Sanam Anoosheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

anoosheh.sanam@icloud.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of melatonin on positive and negative symptoms of schizophrenic patients admitted to

psychiatry ward of Golestan hospital in 2021-2022

Public title

Effect of melatonin in treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have admitted in psychiatry ward of Golestan hospital Age 18-65 years Schizophrenic patient according to DSM-5 Satisfaction of patients' guardianship Schizophrenic patients who have treated with risperidone

Exclusion criteria:

Treatment with any psych medications except for risperidone Comorbidity of other psychopathologies Abuse of any substance, drug, or alcohol Drug reaction to melatonin or placebo Past history of treatment with clozapine or melatonin Pregnancy, mental retardation or any other neurologic and neurocognitive disorders, sleep apnea Proven depression according to Calgary scale Treatment with ECT in the current episode

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the size of the blocks will be equal. The allocation method in each block will be disclosed using the blinding method. Patients admitted to the study in order of referral. Patients will be distributed in a ratio of 1: 1 and by 11 blocks (the length of each block is 4) (sample size of this study is 44). The randomization sequence will be created using the RandomBetween command in Excel.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be treated with medication packages pre-determined by the study supervisor. The drug packages are quite similar in shape and the patient and the executor of the project are not aware of the contents of the packages. In addition, data collection, patient assessment, and completion of forms will be done by the project manager and her assistant who will not be aware of the content of the package. Data analysis will be performed by the project consultant and the project manager who will not be aware of the contents of the drug packages and only the patient group (group 1 or 2)

will be identified for data analysis. Therefore, the study is double-blind and the contents of the two drug groups will not be clear in the patient admission to the study, data collection, and analysis stages.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Sciences

Street address

Golestan hospital , Farvardin Ave , Golestan Blvd

City

Ahwaz

Province

Khuzestan

Postal code

6135733118

Approval date

2021-05-11, 1400/02/21

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.024

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Score of positive and negative symptoms according to PANSS scale

Timepoint

At the start of intervention, 3 weeks and 6 weeks later

Method of measurement

positive and negative syndrome scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients will be treated with melatonin tablet (3 mg) which is prepared in RAZAK drug company. The intervention group will receive two melatonin tablets 3 mg (6 mg in total) 30 minutes before bedtime, for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive placebo tablets, which are similar to melatonin tablets (in shape, smell, taste, size and color) and are made from starch powder with the authorized color by the Pharmacy Laboratory of Ahwaz University of Medical Sciences, for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Forouzan Behruzian

Street address

Golestan hospital , Farvardin Ave , Golestan Blvd

City

Ahwaz

Province

Khuzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Email

anoosheh.sanam@icloud.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Sahand Jorfi

Street address

Ahwaz medical science, Golestan Blvd

City

Ahwaz

Province

Khuzestan

Postal code

6135715794

Phone

+98 61 3333 3477

Email

jorfi-s@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahwaz 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

Ahwaz University of Medical Sciences

Full name of responsible person

Sanam Anoosheh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Golestan hospital , Farvardin Blvd , Golestan

City

Ahwaz

Province

Khuzestan

Postal code

6135733118

Phone

+98 61 3374 3038

Fax

Email

anoosheh.sanam@icloud.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Sanam Anoosheh

Position

Resident

Latest degree

Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Golestan hospital , Farvardin Blvd , Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3038
Fax
Email
anoosheh.sanam@icloud.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sanam Anoosheh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Golestan hospital , Farvardin Blvd , Golestan
City

Ahvaz
Province
Khouzestan
Postal code
6135733118
Phone
+98 61 3374 3038
Fax
Email
anoosheh.sanam@icloud.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