Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigating the effect of Melatonin on the cognitive symptoms of patients with Schizophrenia treated with Risperidone: a randomized double-blind clinical trial

Protocol summary

Study aim
evaluation of corrective modulation of cognitive functions in schizophrenia by short term administration of melatonin , a double blind prospective clinical trial

Design
Two arm parallel group randomized trial with double blinded postoperative care and outcome assessment, phase 3 on 66 patients.

Settings and conduct
Schizophrenic patients admitted in Golestan Hospital's psychiatric department who already are under treatment with risperidone would be divided into two groups: In the intervention group, patients will also receive melatonin tablets at a dose of 6 mg in the form of two 3 mg tablets nightly and In the control group, patients will receive placebo tablets with similar characteristics. The treating psychiatrist, nurse, assistant assessor, and patients would be blinded in randomization process . All measurements for each patient during the entire study would be recorded and checked by an assessor. The cognitive symptoms of the patients would be evaluated by Wechsler's memory questionnaire and investigating cognitive deficits tool , including listening verbal learning, digit symbol substitution test, and verbal fluency test at the beginning, 4 and 6 weeks after the start of the study.

Participants/Inclusion and exclusion criteria
Schizophrenic patients hospitalized in psychiatry department in the age range of 16 to 65 years under risperidone with no history of sensitivity to melatonin.

Intervention groups
added to risperidone , in treatment arm a 6 mg dose of melatonin and in control arm placebo tablets with similar characteristics will be administered daily

Main outcome variables
schizophrenic patients Cognitive symptoms ؛ sleep ؛ metabolic syndrome caused by antipsychotic drugs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230619058537N1**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-09, 1402/04/18**
Update count: **0**

Registration date
2023-07-09, 1402/04/18

Registrant information

Name
Firouzeh Mohtasham zadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-25, 1402/04/04

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Melatonin on the cognitive symptoms of patients with Schizophrenia treated with Risperidone: a randomized double-blind clinical trial

Public title
The effect of Melatonin in Schizophrenia treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients admitted in the Psychiatric department of Ahvaz Golestan Hospital, who are in the age range of 16 to 65 years Diagnosis of schizophrenia based on DSM-5 criteria Informed consent of the patients or their guardian to participate in a research project Schizophrenic patients treated with risperidone

Exclusion criteria:
Taking typical and atypical antipsychotic drugs, except for Risperidone, antidepressants, Sodium valproate, and Lithium. Presence of comorbid psychiatric disorder (bipolar-psychotic, obsessive-compulsive disorder, post-traumatic stress disorder, eating disorder) Current or past diagnosis (last 6 months) of severe personality disorders that compromise the participant's ability to meet the requirements. Use of narcotic drugs or alcohol in the last 12 months, except for nicotine and caffeine Presence of mental retardation or other neurological cognitive disorders such as dementia, delirium, head trauma, seizures, obstructive sleep apnea. History of ECT in the past 6 months In case of serious complications, the patient will be excluded from the study. Hypersensitivity to Melatonin or any of the ingredients in the placebo Use of Clozapine or previous use of Melatonin based on medical history obtained Pregnancy , lactating women Diagnosing the depressive episode of schizophrenia based on the Calgary questionnaire

Age
From **16 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: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the size of the blocks will be equal, and in order to prevent the disclosure of the allocation in each group, the blinding method will be used. Patients are included in the study in order of referral. Patients will be distributed with a ratio of 1:1 and by 11 blocks (the length of each block is 6) (the sample size of this study is 66). The randomization sequence will be done using the randomization process method by Microsoft excel (Random between)

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, patients will take medication packages predetermined by the study supervisor. The drug packages are completely similar in terms of shape and the patient and the project manager are not aware of their contents. In addition, the collection of information, assessment of patients and completion of forms are done by the project manager and his assistant, who are not aware of the contents of the medication packages used by patient. The data analysis stage will also be done by the project manager, and only the patient group (group 1 and 2) will be determined for data analysis. Therefore, this study plan would be double-blinded, and during patient allocation , data collection and information analysis contents of drugs packages would be hidden for all participants.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Psychiatry Dep, Golestan Hospital, Farvardin Ave ,Golestan Blvd

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Approval date
2023-06-18, 1402/03/28

Ethics committee reference number
IR.AJUUMS.REC.1402.164

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description
Cognitive symptoms of schizophrenia
Timepoint
First, 4 and 6 weeks after the study
Method of measurement
Wechsler Memory Questionnaire, Cognitive impairment investigation via review of auditory verbal learning, Digit symbol substitution test, Fluency test.

Secondary outcomes

1

Description
sleep-wake disorders
Timepoint
First, 4 and 6 weeks after the start of the study
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Intervention groups

1

Description
Intervention group: In addition to the second-generation antipsychotic drug (risperidone) that they have already taken, the patients receive two 3 mg melatonin tablets at the same time (6 mg in total) for 6 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients receive a placebo tablet, which is similar to melatonin tablets (in terms of shape, smell, taste, size, and color) and starch powder with an approved color as needed made by the pharmaceutical laboratory of the Faculty of Pharmacy of Ahvaz 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 Behroozian
Street address
Golestan Hospital, Farvardin Street, Golestan Blvd
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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
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
Behrouzian Forouzan
Position
Assistant professor
Latest degree
Specialist

Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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