Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of agomelatine on positive and negative symptoms of schizophrenic patients admitted to the psychiatry ward of Golestan hospital

Protocol summary

Study aim

Evaluating the effect of agomelatine on positive and negative symptoms of schizophrenic patients admitted to the psychiatry ward of Golestan Hospital

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 1-2 on 22 patients. The patients were randomized by random permutation blocks with a block size of 6 (using the table related to random permutations).

Settings and conduct

This study will be conducted in the psychiatry department of Ahvaz Golestan Hospital in a blinded manner, where the treating psychiatrist, nurse student evaluator and patients are not aware of the intervention and control groups. In addition to prescription antipsychotic treatment, patients will receive agomelatine tablets (Tadbir Kalai Jam Pharmaceutical Company) (one 25 mg tablet 30 minutes before bedtime) in the intervention group and placebo tablets in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients diagnosed with schizophrenia according to DSM-5 criteria, Calgary Schizophrenia Depression Score (CDSS), positive symptom subscale score of PANSS. Conditions of non-entry: use of typical antipsychotic drugs and antidepressants, sodium valproate, lithium, and benzodiazepines, presence of accompanying psychiatric disorders such as schizoaffective or other psychotic disorders.

Intervention groups

Intervention group: prescription antipsychotic treatment with agomelatine tablets (Tadbir Kalai Jam Pharmaceutical Company), in the form of one 25 mg tablet 30 minutes before bedtime. Control group: Prescription antipsychotic treatment, and placebo tablets, which are similar to agomelatine tablets in terms of shape, smell, taste, size and colour, will be received in the same way as the intervention group.

Main outcome variables

5-DSM, CDSS, PANSS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240805062662N1**
Registration date: **2024-08-31, 1403/06/10**
Registration timing: **prospective**

Last update: **2024-08-31, 1403/06/10**
Update count: **0**

Registration date

2024-08-31, 1403/06/10

Registrant information

Name

Tahereh Amirshekari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 368 7265

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-05, 1403/06/15

Expected recruitment end date

2024-10-06, 1403/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of agomelatine on positive and negative symptoms of schizophrenic patients admitted to the psychiatry ward of Golestan hospital

Public title

The effect of agomelatine on positive and negative symptoms of schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with schizophrenia based on DSM-5 criteria Calgary Schizophrenia Depression Score (CDSS) ≤ 18 PANSS positive symptoms subscale score is greater than 7 and less than or equal to 28. PANSS negative symptoms subscale score greater than or equal to 24 and at least 2 of the 3 main symptoms (emotional boredom, passive/indifferent social withdrawal and lack of spontaneity and fluency in conversation) have ≥ 4 points.

Exclusion criteria:

Taking typical antipsychotic drugs, antidepressants, sodium valproate, lithium, and benzodiazepines The presence of accompanying psychiatric disorders such as schizoaffective or other psychotic disorders, bipolar disorder, anxiety disorders such as panic disorder or obsessive-compulsive disorder, post-traumatic stress disorder, eating disorder Current or past (past 6 months) diagnosis of severe personality disorders that would compromise the participant's ability to perform the study requirements. Hypersensitivity to agomelatine or any of the ingredients of the placebo

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

To the patients randomly and by the method of randomized permutation blocks with a block size of 6 (using the table related to random permutations). A statistician will prepare a random list. The interventions used in this research will be placed in sealed envelopes according to the randomized list by someone outside the study according to the corresponding codes, and then each patient who will enter the study; will be assigned

Blinding (investigator's opinion)

Double blinded

Blinding description

The treating psychiatrist, nurse student evaluator and patients are not aware of the intervention and control group.

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

Ground floor, Vice-Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University City, Golestan street, Ahvaz, Iran.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2024-05-25, 1403/03/05

Ethics committee reference number

IR.AJUMS.REC.1403.097

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

5-DSM

Timepoint

Before the intervention, 2 and 4 weeks after the intervention

Method of measurement

Interview

2

Description
CDSS
Timepoint
Before the intervention, 2 and 4 weeks after the intervention
Method of measurement
Interview

3

Description
PANSS
Timepoint
Before the intervention, 2 and 4 weeks after the intervention
Method of measurement
Interview

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the prescribed antipsychotic treatment that they were already taking, patients receive agomelatine tablets (Tadbir Kalaye Jam Pharmaceutical Company) in the form of one 25 mg tablet 30 minutes before going to sleep.
Category
Treatment - Drugs

2

Description
Control group: In addition to prescribed antipsychotic treatment, patients receive placebo tablets, which are similar to agomelatine tablets in terms of shape, smell, taste, size, and color, and are prepared by the Faculty of Pharmacy of Ahvaz University, in the same way as the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry Department of Golestan Hospital
Full name of responsible person
Tahereh Amirshekari
Street address
Psychiatry Department of Golestan Hospital, Golestan Steet, Ahvaz, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
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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
Tahereh Amirshekari
Position
Resident
Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Psychiatry Department of Golestan Hospital, Golestan Steet, Ahvaz, Iran.

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable