Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effectiveness of adding modafinil drug on negative symptoms of schizophrenic patients being treated with risperidone or olanzapine

Protocol summary

Study aim
The effectiveness of adding modafinil drug on negative symptoms of schizophrenic patients being treated with risperidone or olanzapine

Design
The clinical trial study includes two intervention and control groups, 21 people in each group are randomly assigned. The method used is block randomization.

Settings and conduct
This study will be conducted on patients hospitalized in Ahvaz Golestan Hospital. The patients and the evaluator do not know the type of medicine received.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients between 18 and 65 years old, schizophrenic patients who have been treated with risperidone or olanzapine, patients diagnosed with schizophrenia based on DSM-5 criteria. Exclusion criteria: taking typical antipsychotic and atypical antipsychotic drugs except risperidone and olanzapine and antidepressants and sodium valproate and lithium and benzodiazepines, 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, dependence or abuse of substances, drugs or alcohol acutely or in the past 12 months, except for nicotine, sensitivity to modafinil or any of the placebo compounds.

Intervention groups
Intervention group: in the intervention group, patients will receive 100 to 200 mg of modafinil tablets per day for 4 weeks in addition to the prescribed antipsychotic treatment (resperidone or olanzapine) that they were already taking. Control group: in the control group, in addition to prescribed antipsychotic treatment, the patients were given a placebo pill that is similar to Modafinil in terms of shape, smell, taste, size and color and was prepared by the Ahvaz University in the same way as the intervention group will receive

Main outcome variables
Negative symptoms

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161228031626N6**
Registration date: **2023-07-15, 1402/04/24**
Registration timing: **prospective**

Last update: **2023-07-15, 1402/04/24**
Update count: **0**

Registration date
2023-07-15, 1402/04/24

Registrant information

Name
Hatam Boostani
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 61 3374 3038
Email address
tabibi.y@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-08-01, 1402/05/10
Expected recruitment end date
2023-10-02, 1402/07/10
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of adding modafinil drug on negative symptoms of schizophrenic patients being treated with risperidone or olanzapine

Public title

The effectiveness of adding modafinil drug on negative symptoms of schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with schizophrenia based on DSM-5 criteria Schizophrenic patients who have been treated with risperidone or olanzapine.

Exclusion criteria:

Taking typical antipsychotic and atypical antipsychotic drugs, except for risperidone and olanzapine, and 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 Dependence or abuse of substances, drugs or alcohol, acutely or in the past 12 months, except for nicotine Allergy to Modafinil or any of the placebo ingredients

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to divide patients into two groups, the randomized block method is used. In this method, group A is related to the intervention and group B is considered as the control and is classified into 4 blocks including AABB, ABAB, ABBA, BBAA, BABA, BAAB, according to the selected permutations. The patient is classified into one of the intervention or control groups. Random allocation software was used for randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the project manager and the patient are unaware of which of the two groups will receive which drug or placebo. Medicines and placebos will be similar in terms of shape, color, smell and taste.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of ahvaz University of Medical Sciences

Street address

Ahvaz Jondishapur University of Medical Sciences, Esfand ave, Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.AJUMS.REC.1402.216

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Negative symptoms

Timepoint

Before and 4 weeks after the study

Method of measurement

Scale for Assessment of Negative Symptoms (SANS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients will receive 100 to 200 mg of modafinil per day for 4 weeks in addition to the prescribed antipsychotic treatment (resperidone or olanzapine) they were already taking.

Category

Treatment - Drugs

2

Description

Control group: In this group, in addition to the prescribed antipsychotic treatment, the patients were given a placebo pill that was similar to Modafinil in terms of shape, smell, taste, size and color and was prepared by the Faculty of Pharmacy of Ahvaz University in the same way as the intervention group for 4 weeks will receive

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Golestan hospital

Full name of responsible person
Maryam Khalafi

Street address
Golestan Hospital, Golestan Blvd., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3001

Email
peymann_600@mail.ru

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mehrnoosh Zakerkish

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3374 3001

Email
zakerkish.m@ajums.ac.ir

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
Hatam Boostani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3001

Email
boostani-h@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Hatam Boostani

Position
Associate professor

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boostani-h@ajums.ac.ir

Person responsible for updating data

Contact

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Ahvaz University of Medical Sciences

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Maryam Khalafi

Position
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City
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Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3001

Email
peymann_600@mail.ru

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
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
No - There is not 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