Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of betahistine on prevention of olanzapine-induced weight gain in patients with psychotic disorder

Protocol summary

Study aim
Determining the effect of betahistine on olanzapine-induced weight gain in patients with psychosis

Design
Clinical trial with control group, with parallel, randomized, phase 2 and 3 groups on 120 patients. The permutation block method was used for randomization.

Settings and conduct
This double-blind study will be performed to determine the effect of betahistine on olanzapine-induced weight gain in patients with psychosis in Sabzevar Avasei Hospital. Patients will be randomly assigned to the control and intervention groups. For the control group, the usual treatment of olanzapine alone and for the intervention group, in addition to the usual drug olanzapine, he will prescribe betahistine tablets. Patients in both groups take 5 to 10 mg of olanzapine daily for 73 days, and in these 73 days in the intervention group, betahistine at a dose of 8 mg twice daily (a total of 16 mg daily) with olanzapine will be used. In this study, the participants in the project and the person implementing the project (researcher) were kept blind.

Participants/Inclusion and exclusion criteria
Not all people with psychosis are treated with olanzapine and do not take effective histamine receptors (antihistamines, etc.).

Intervention groups
We had 60 people in the intervention group (olanzapine + betahistine) and 60 people in the control group (olanzapine alone). Patients in both groups take 5 to 10 mg of olanzapine daily for 73 days, and in these 73 days in the intervention group, betahistine 8 mg twice daily (16 mg daily) was also taken.

Main outcome variables
Weight: the rate of weight gain; Waist circumference: The rate of increase in waist circumference

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210409050910N2**
Registration date: **2022-04-13, 1401/01/24**
Registration timing: **retrospective**

Last update: **2022-04-13, 1401/01/24**
Update count: **0**

Registration date
2022-04-13, 1401/01/24

Registrant information

Name
HOSEIN FAHIMI

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4467 2987

Email address
hossein1fahimi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
2021-05-22, 1400/03/01

Actual recruitment end date
2022-02-20, 1400/12/01

Trial completion date
2022-03-01, 1400/12/10

Scientific title

The effect of betahistine on prevention of olanzapine-induced weight gain in patients with psychotic disorder

Public title
The effect of betahistine on prevention of olanzapine-induced weight gain in patients with psychotic disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Not all people with psychosis are treated with olanzapine and do not take effective histamine receptors (antihistamines, etc.).
Exclusion criteria:
Patients with concomitant metabolic diseases Patients who are obese. Patients taking other weight gain drugs (such as clozapine) at the same time.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is performed as a clinical trial on psychotic patients under standard treatment with olanzapine referred to the medical center of Vasei hospital in Sabzevar after the approval of the ethics committee and obtaining informed written consent of patients referred to the psychiatric clinic of Vasei hospital under the supervision of psychiatric professors. People who have been diagnosed with psychosis according to the DSM5 criteria and are being treated with olanzapine will be selected. After randomization, we will have 60 people in the intervention group (olanzapine + betahistine) and 60 people in the control group (olanzapine alone). Patients in both groups take 5 to 10 mg of olanzapine daily for 73 days, and in these 73 days in the intervention group betahistine at a dose of 8 mg twice a day (16 mg daily) with the start of treatment at the end of treatment in the group. Intervention and in the control group, weight is measured with a specific scale and waist circumference is measured with a meter, and the two groups are compared in terms of weight and waist changes.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Road of Tohid shar- Pardis of Sabzevar University of Medical Sciences
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873119
Approval date
2020-02-10, 1398/11/21
Ethics committee reference number
IR.MEDSAB.REC.1398.117

Health conditions studied

1

Description of health condition studied
Psychosis
ICD-10 code
F29
ICD-10 code description
Unspecified psychosis not due to a substance or known physiological condition

Primary outcomes

1

Description
Weight: The rate of weight gain in control and intervention groups
Timepoint
Start treatment, weeks 4 and 8 and end treatment
Method of measurement
Scales

2

Description
Waist circumference: The rate of increase in waist circumference in control and intervention groups
Timepoint
Start treatment, weeks 4 and 8 and end treatment
Method of measurement
Meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment + betahistine, patients take 5 to 10 mg of olanzapine daily for 73 days and in these 73 days in the intervention group, betahistine 8 mg twice a day (16 mg daily) with olanzapine will be used.
Category
Treatment - Drugs

2

Description
Control group: Routine treatment, Patients take 5 to 10 mg of olanzapine daily for 73 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasei Hospital
Full name of responsible person
Hossein Fahimi
Street address
Tohid Shahr Boulevard - Vasei Hospital
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Razavi Khorasan
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https://www.medsab.ac.ir/index.aspx?siteid=1&fkeyid=&siteid=1&pageid=9388

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Hossien Saghi
Street address
Sabzevar, Tohidshahr Boulevard, above the Tomb of the Unknown Martyrs, University Campus Building, Vice Chancellor for Education
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Grant name
Mohammad Hossien Saghi
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Hossein Fahimi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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