

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

City

Sabzevar

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Phone

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Email

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Web page address

<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

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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

Person responsible for updating data**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

Psychiatrics