

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Betahistine on Weight- related and Metabolic Measures in Patients with Schizophrenia Treated with Olanzapine and Risperidone

Protocol summary

Study aim

Determine the Effect of Betahistine on Weight-related and Metabolic Measures in Patients with Schizophrenia Treated with Olanzapine and Risperidone

Design

Randomised, concealed, superiority, parallel group clinical trial. This trial is double blind (for patients and researcher), and divided into two groups that each group has 28 patients. Randomisation was done with site or excel software.

Settings and conduct

This Study is performed by Resident of psychiatry in Schizophrenic patients hospitalized and outpatients of Ebnesina Hospital and Hejazi Hospital who are taking Olanzapine or Risperidone. They are randomly divided into intervention (receive Betahistine) or control group (receive Placebo). It's Double blind. Patients and Researcher are not aware about drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Have Schizophrenia Based on DSM5 -18-59 years old - Treated with Olanzapine or Risperidone that it doesn't Change during the Study - Weight gain at least 7% of total body weight in the first year of Treatment with Anti Psychotics or in a recent year
Exclusion criteria: Pregnant or Lactating Allergy to Betahistine -Asthma, Peptic ulcer, Pheochromocytoma, Liver and Kidney Disfunction

Intervention groups

Patients are divided into two groups receiving Olanzapine and Risperidone. In both groups The intervention group treated with Betahistine (starting with 8 milligram and reaching 48 milligram within 11 days). The control group received Placebo which is quite similar to Betahistine.

Main outcome variables

Weight, Waist and Hip circumference, BMI, Fasting blood sugar, Lipid profile including cholesterol and triglyceride, Thyroid stimulating hormone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191223045870N1**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **prospective**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Najmeh Abbasi Janet abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 1014

Email address

najmeabbasi84@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Betahistine on Weight- related and Metabolic Measures in Patients with Schizophrenia Treated with Olanzapine and Risperidone

Public title

Betahistine and Weight- Related and Metabolic Measures in schizophrenic Patients Treated with Olanzapin or Risperidone

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient or Legal Guardian Informed Consent Have Schizophrenia Based on DSM5 18-59years old Treated With Olanzapine or Risperidone That It Dosen't Change During The Study Weight Gain At Least 7% Of Total Body Weight In The First Year of Treatment With Anti Psychotics Or In a Resent Year If The Patient Is Taking Medication For Hyperlipidemia or Hypertention or Tyroid Disorders The Dose of Medication Did not Changed During The Study The Patients Do not Have Another Medical or Psychiatric Disease Do not Use Substance (Except Nicotine)

Exclusion criteria:

Have Asthma Have Peptic Ulcer Have Pheochromocytoma Liver and Kidney Disfunction Treated with Other Weight Related Medications Like Sodium Valproarte or Weight loss or Appetite Suppressant Medications Have Allergy to Betahistine Pregnant or Lactating

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with inclusion criteria devided into two groups receiving risperidone or olanzapine.(Stratified randomization). Then random numbers selected for each group with Excel software or other randomization sites (Simple randomization) and packed in envelopes (Allocation concealment).

Blinding (investigator's opinion)

Double blinded

Blinding description

For the patient with entry requirements after obtaining consent from him/her or him/her legal guardian an envelope is opened.Depending on the type of allocation of even / odd or A/B they fall into intervention or control group and medicine is given to the patient or his/her legal guardian and explained how to use that.The researcher records the patient's name, the date of first referral and the delivered product code.Patients do not

know which group they are in.(Patients are blind).The researcher conducts follow- up as scheduled and she does not know which group the patien is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of Medical Sciences

Street address

Ebne sina Hospital.,Toos Blvd., Mashhad Town

City

mashhad

Province

Razavi Khorasan

Postal code

9190983117

Approval date

2019-12-18, 1398/09/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.684

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Weight Related Measures(weight,waist and Hip circumference,BMI)

Timepoint

At The Begining of the Study Then Every Month

Method of measurement

Weight measure with scales, Waist and Hip circumference measure with Meter

2

Description

Fasting blood sugar

Timepoint

At the Beginning of The Study And After 12 weeks

Method of measurement

Laboratory Glucose kit

3

Description

Lipid profile include cholesterol and tri glyceride

Timepoint

At the Beginning of The Study And After 12 weeks

Method of measurement

Laboratory cholestrol and triglycerid kits

4

Description

Thyroid stimulating hormone

Timepoint

At the Beginning of The Study And After 12 weeks

Method of measurement

Enzyme linked immunosorbent test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the intervention group received second generation of antipsychotics (Olanzapine or Risperidone) as a routine treatment and Betahistine (as an intervention), from 8 milligram then it would reach to 48 milligram in 11 days and it will remain in this dose until the end of the study (12 weeks).

Category

Prevention

2

Description

Control group: The control group received second generation of antipsychotics (Olanzapine or Risperidone) as a routine treatment Placebo (similar to Betahistine in shape and color) . (In order to keep patients blind in this study, as one Betahistine pill is added to intervention group every two days to achieve the 48 mg/d in 11th day of intervention, the number of placebo prescribed to control group would be increased till the eleventh day and then fixed till the end of the study).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebnesina Hospital

Full name of responsible person

Najmeh Abbasi Jannatabadi

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Ebnesina Hospital.,Horeameli Ave.,Toos Blvd.,Mashhad Town

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2

Recruitment center

Name of recruitment center

Hejazi Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Mashhad 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
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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)

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