

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The study of efficacy of Empagliflozin on metabolic effects of atypical antipsychotic drugs in patients with psychiatric disorders: a randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of empagliflozin on metabolic side effects of atypical antipsychotic drugs in patients with mental disorders treated with these drugs

Design

Clinical trial with parallel, double-blind, randomized block-based groups consisting of 40 patients, study phase 3.

Settings and conduct

Forty patients with DSM-V-TR-based mental disorders who are not pregnant or breastfeeding were included in the study based on inclusion and exclusion criteria and were randomly divided into two groups of 20 intervention and control (intervention group: group receiving atypical antipsychotics such as olanzapine, clozapine, and risperidone in combination with empagliflozin 10 mg daily; and control group: the group receiving atypical antipsychotic medication alone) for 12 weeks. Both groups at the beginning, fourth week, eighth week and end of the study in terms of metabolic indicators including blood pressure, body weight, body mass index (BMI), distance, comparison profile (LDL-HDL-TG) and FBS; Will be checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18 - 65 years old Diagnosis of mental disorders with psychosis and psychotic disorders Stable treatment with atypical antipsychotics (olanzapine, clozapine and risperidone). Stable body weight. (BMI \geq 25) Exclusion criteria: Pregnancy and lactation A recent history of drug abuse or dependence Hepatic failure Renal insufficiency (GFR less than 30) Having type 1 or 2 diabetes Dysfunction of the pancreas Cardiovascular disease Uncontrollable blood pressure Treatment with corticosteroids or other hormone therapy

Intervention groups

Receiving atypical antipsychotics such as olanzapine, clozapine, and risperidone in combination with

empagliflozin 10 mg daily

Main outcome variables

Metabolic indicators include blood pressure, body weight, body mass index (BMI), waist circumference, LDL-HDL-TG and FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039187N9**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Elnaz Shaseb

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of efficacy of Empagliflozin on metabolic effects of atypical antipsychotic drugs in patients with psychiatric disorders: a randomized clinical trial

Public title

Evaluation effect of Empagliflozin in psychiatric disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 18 - 65 years old Diagnosis of mental disorders with psychosis and psychotic disorders based on DSM-V-TR Stable treatment with atypical antipsychotics (olanzapine, clozapine and risperidone) in the last 6 months (no dose change in the last 30 days) Stable body weight (definition: less than 5% weight change in the last three months before the trial) Body mass index greater than or equal to 25 ($BMI \geq 25$)

Exclusion criteria:

Pregnancy and lactation A recent history of drug abuse or dependence Hepatic failure (increase in liver trans aminases to 2 times normal) Renal insufficiency (GFR less than 30) Having type 1 or 2 diabetes Dysfunction of the pancreas Cardiovascular disease Uncontrollable blood pressure Treatment with corticosteroids or other hormone therapy Use medication to lose weight in the last 3 months

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AAB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AAB(1)_BBAA(4)_ABAB(2)_BABA(5)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants (patients) and the researcher who have the task of sampling in the study are all blind during the

study. At the patient's level, blindness will be done as the patients do not know in which group (control or intervention group) they are in. The researcher on the basis of table A or B without knowing the nature of A, B and according to the randomized list will give the medicine to patients or not.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz

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Tabriz

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Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.TBZMED.REC.1400.847

Health conditions studied**1****Description of health condition studied**

psychiatric disorders

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Blood pressure

Timepoint

The beginning of the study, the fourth week, the eighth week and the end of the study

Method of measurement

using a sphygmomanometer

2

Description

Body weight

Timepoint

The beginning of the study, the fourth week, the eighth week and the end of the study

Method of measurement

Using digital scale

3

Description

Waist circumference

Timepoint

The beginning of the study, the fourth week, the eighth week and the end of the study

Method of measurement

Using a plastic meter

4

Description

LDL-HDL-TG

Timepoint

The beginning and the end of the study

Method of measurement

Laboratory tests (enzymatic)

5

Description

FBS

Timepoint

The beginning and the end of the study

Method of measurement

Laboratory tests (enzymatic)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take atypical antipsychotic drugs such as olanzapine, clozapine and risperidone with empagliflozin 10 mg daily

Category

Treatment - Drugs

2

Description

Control group: Atypical antipsychotic medications such as olanzapine, clozapine, and risperidone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital of Tabriz

Full name of responsible person

Zahra Mousavi MD

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Shahid Bakeri Boulevard (Ail Goli)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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No. 2, Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Azadi Ave.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

30

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Elnaz Shaseb

Position

Member of the faculty of clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position

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Other areas of specialty/work

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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