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 ampagliflozin 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 ampagliflozin 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≥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 ampagliflozin 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

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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≥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 AABB(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: AABB(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 lable A or B without knowing the nature of A, B and according to the randomized list will give the medicine to pateints 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
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
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 ampagliflozin 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
Street address
Shahid Bakeri Boulevard (Ail Goli)
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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?
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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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