Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

determination of Empagiflozin effect as an adjunct therapy for treatment of Major depressive disorder in a double blind placebo control clinical trial by using Hamilton questionnaire

Protocol summary

Study aim

The aim of this study is determination of Empagliflozin effect as an adjunct therapy for treatment of MDD, comparison between the treatment of patients who received Empagliflozin and placebo

Design

The clinical trial is randomized double-blind . The sample size is 80 people, half of them will receive citalopram plus Empagliflozin and the other half will receive citalopram plus placebo.

Settings and conduct

This clinical trial is carried out in psychiatric clinic of Imam Ali Hospital , MDD known cases with inclusion criteria and w/o exclusion criteria will be chosen and as a randomized double blinded trial (physician and patient do not know which category the patient is) half of patients receive Citalopram and Empagliflozin and the other half receive Citalopram and Placebo.and their Ham score is assessed in weeks 0 4 8.

Participants/Inclusion and exclusion criteria

inclusion requirements: MDD diagnosed (Ham. score>22) exclusion requirements: Psychotic/Other disorders in axes I or II/Psychotropic medicine/Anti depressant agents use during last one month and ECT during last 2 months. Hypothyroidism/Cardiovascular disease history/Pregnancy or breast feeding Kidney disease/DM type 1/age<18 or >60/IQ<70/seizure and neurologic disorders/Betablockers use/Drug abuse except nicotine and caffeine/ UTI/Mao inhibitors use such as Azilect ,Marplan ,Aspirin ,Gabapentin , Pantoprazole ,Omeprazole/Pancreatitis/Hypotension

Intervention groups

40 volunteers receive daily Citalopram and Empagliflozin and 40 volunteers receive daily Citalopram and Placebo. .Their Hamilton score will be evaluated in Weeks 0 and 4 and 8 . The change in depression severity is assessed using Hmailton test during 2 months.

Main outcome variables

Hamilton's score is the main variable of the study and determines the effectiveness of the drug and shows us how well the patient's depression has improved.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200805048313N1**
Registration date: **2022-02-10, 1400/11/21**
Registration timing: **prospective**

Last update: **2022-02-10, 1400/11/21**
Update count: **0**

Registration date

2022-02-10, 1400/11/21

Registrant information

Name

atefe zabdifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 26 3255 4432

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

determination of Empagiflozin effect as an adjunct therapy for treatment of Major depressive disorder in a double blind placebo control clinical trial by using Hamilton questionnaire

Public title

determination of Empagiflozin effect as an adjunct therapy for treatment of Major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with MDD based on DSM V criteria while Hamilton score is equal to 22 or more than 22.

Exclusion criteria:

Being psychotic Having Other disorders in axis 1 or 2 Using other psychedelic drugs Has taken Anti depressant agents in last month Or ECT in the 2 last months. Hypothyroidism Positive Cardiovascular disease history Pregnancy or Lactation Renal disease Diabetes type 1 Age < 18 or Age>60 years old IQ <70 Medical history of seizure and CNS disorders Using Betablocker agents Using drugs rather than Nicotine and Caffeine Urinary tract infection Mao inhibitors such as Azilect ,Marplan ,Aspirin ,Gabapentin , Pantoprazole ,Omeprazole Pancreatitis Hypotension

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

By using a computerized random number generator, study subjects will be randomized in a 1 : 1 ratio in blocks of four to receive either Empagliflozin or placebo in addition to their standard treatment.in this method the subjects receiving Empagliflozin or placebo will be chosen by the system. In this study randomized allocation of the two intervention groups(drug or placebo) in standard time will be done by permuted balance block technique. the considered blocks of this study will be blocks of four. A series of randomized numbers of 1 to 6 is produced by using "Envelope" application . preparing randomized allocated series of interventional groups and putting them in stapled ,sealed and opaque envelopes with 5 digit serial number ,will be done by a third person who has no role in the study. All envelopes have a 5 digit serial number which will be immediately opened after entry of each volunteer in the study and the patients will be divided into two groups of Drug and Placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blinded clinical trial .Allocation concealment will be done using sequentially numbered, sealed, opaque, and stapled envelopes. Separate persons are responsible for randomization and allocation, as well as interviewing. The physician who refers the patient, the patients, the resident who administer the drugs and rated the patients, and the statistician will be blinded to allocation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

vice president for research of Alborz university of medical sciences, Saffarian alley, Golshahr St., Karaj

City

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Province

Alborz

Postal code

3198764653

Approval date

2021-12-19, 1400/09/28

Ethics committee reference number

IR.ABZUMS.REC.1400.275

Health conditions studied

1

Description of health condition studied

Major depression disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

Primary outcomes

1

Description
Hamilton score
Timepoint
1st visit and 4 and8 weeks after Empagliflozin/Placebo administration
Method of measurement
Hamilton score questionnaire

Secondary outcomes

1

Description
Hamilton score
Timepoint
1st day 4th week and 8th week after administration of Empagliflozin /Placebo
Method of measurement
24 question Hamilton test

Intervention groups

1

Description
Control group: 40 patients who receive Placebo similar to the main medicine from any aspect (taste, color and shape). they receive placebo(once daily)in addition to their standard MDD treatment(Citalopram 40 mg oral agent) for 2 months.
Category
Treatment - Drugs

2

Description
Intervention group: 40 patients who receive Empagliflozin (10 mg once daily from Abidi Company) in addition to their MDD standard treatment(Citalopram 40 mg once daily) for 2 months; both as oral agent.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali hospital
Full name of responsible person
Maryam Panahi
Street address
NO.20, 3rd west alley, Mersad street,Sepehr St. Farahzadi Blvd. Shahrak Gharb, Tehran
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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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Research deputy of Alborz university of medical sciences, Saffarian alley, Golshahr st. ,Karaj, Alborz
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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
Research deputy of Alborz 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
Karaj University of Medical Sciences
Full name of responsible person
Dr Atefeh Zandifar
Position
associate professor
Latest degree
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All findings from this trial will be made public. In order to publish it, patients' personal information and their names will not be disclosed, but all scientific information will be made available to the public.

When the data will become available and for how long

Public access will be established up to six months after the end of the study.

To whom data/document is available

The public and those interested in scientific information will have access to this trial findings.

Under which criteria data/document could be used

All statistical analysis and classified information will be provided to them.

From where data/document is obtainable

If requested, please refer to mary.pn96@gmail.com e-mail.

What processes are involved for a request to access data/document

The applicant can use the information within 24 hours if the request for the results of our study is announced at the email address mentioned.

Comments