Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Effect of Empagliflozin and Topiramate co-administration on anthropometric indices and metabolic markers in individuals with excess weight on a calorie restricted diet

Protocol summary

Study aim

Determining the effect of Empagliflozin and Topiramate co-administration on anthropometric indices and metabolic markers in individuals with excess weight on a calorie restricted diet

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 44 patients

Settings and conduct

In this study, individuals with excess wight referring to the obesity clinic, Tehran are asked to complete a written informed consent form. Individuals will be randomly assigned to one of the intervention or placebo groups. At baseline and end of the study, anthropometric indices will be measured. Also, 10 cc of blood will be taken from participants and glucose and lipid profiles as well as inflammatory factors will be determined. Empagliflozin and topiramate tablets and their placeboes will be placed into identical containers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women >18 years; with body mass index 30-40 kg/m2 with or without hypertension and/or dyslipidemia, or body mass index 27-30 kg/m2 with hypertension and/or dyslipidemia; without diabetes. Exclusion criteria: Not comply with intervention or diet

Intervention groups

Intervention group: 22 Individuals with excess weight and without diabetes receive calorie restricted diet (with 500 kcal less than energy required) with an empagliflozin (10 mg) and topiramate (25 mg/day in the first week of intervention and if tolerated by the participants, the dose will increase to 50 mg/day (BD) from the second week till end of the intervention), daily, for 12 weeks. Placebo group: 22 individuals with excess weight and without diabetes receive calorie restricted diet (with 500 kcal less than energy required) with a placebo of empagliflozin and topiramate, daily.

Main outcome variables

The primary outcomes in this study are changes in weight and percentage of fat mass.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230114057122N1**
Registration date: **2023-02-13, 1401/11/24**
Registration timing: **retrospective**

Last update: **2023-02-13, 1401/11/24**
Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Behnaz Abiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

abiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

2022-07-23, 1401/05/01

Actual recruitment end date
2023-01-20, 1401/10/30
Trial completion date
2023-03-19, 1401/12/28

Scientific title
Effect of Empagliflozin and Topiramate co-administration on anthropometric indices and metabolic markers in individuals with excess weight on a calorie restricted diet

Public title
Effect of Empagliflozin and Topiramate co-administration in individuals with excess weight on a calorie restricted diet
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Men and women over 18 years of age; with body mass index 30-40 kg/m2 with or without hypertension and/or dislipidemia, or body mass index 27-30 kg/m2 with hypertension and/or dislipidemia; without diabetes or eating disorders; not taking vitamin and mineral supplements; not being pregnant or breastfeeding.
Exclusion criteria:
Exclusion criteria: Any type of acute illness during the study; not comply with intervention or diet (less than 80% compliance)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomized allocation performing, permuted block randomization will be used by blocks with size of 4. According to the sample size of 44 subjects, 11 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will be entered into the study based on the produced sequence. The drug packets will be allocated to the individual with code on them. Therefore, participants will be unaware of the type of intervention that will receive, as well as the random sequence which will be hidden and unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to performing the double-blinded of the study, before the study beginning, the containers containing tablets will be provided by someone other than the researchers, and the placebo tablets in appearance are similar to the tables and the researchers are not aware about the allocation of studied subjects in each group during the evaluation of the outcomes until the end of the intervention period.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi Street, Velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-06-26, 1401/04/05
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.137

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Anthropometric indices
Timepoint
Before the intervention and 12 weeks after intervention
Method of measurement
The height will be measured with a stadiometer at a standing position, body weight will be measured using a Beurer scale (Beurer, Germany), The waist circumference is measured with inflexible tape measure. The

percentage of body fat mass will be determined by bioelectrical impedance analysis (Quad scan 4000; Bodystat).

Secondary outcomes

1

Description
Fasting blood glucose
Timepoint
Before the intervention and 12 weeks after intervention
Method of measurement
Fasting blood glucose levels will be measured using ELISA method.

Intervention groups

1

Description
Intervention group: A calorie restricted diet (with 500 kcal less than energy required) with an empagliflozin (10 mg) and topiramate (25 mg/day in the first week of intervention and if tolerated by the participants, the dose will increase to 50 mg/day (BD) from the second week till end of the intervention), daily.
Category
Treatment - Drugs

2

Description
Control group: A calorie restricted diet (with 500 kcal less than energy required) with a placebo of empagliflozin and topiramate, which are similar in appearance to empagliflozin and topiramate, daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Clinic of Taleghani Hospital
Full name of responsible person
Majid Valizadeh
Street address
Arabi Street, Velenjak
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Tehran
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1985717413
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+98 21 2243 2500
Email
valizadeh@endocrine.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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1985717443
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info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Majid Valizadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Behnaz Abiri

Position

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Latest degree

Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

A part of the data will be shared, such as primary outcomes

When the data will become available and for how long

Six months after the publication of the results

To whom data/document is available

Researchers and students of university

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran. Phone number: 0098 21 22432500. E-mail: valizadeh@endocrine.ac.ir

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

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran. Phone number: 0098 21 22432500. E-mail: valizadeh@endocrine.ac.ir

Comments