

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 weight 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 placebos 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@sbm.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

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Arabi Street, Velenjak

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1985717413

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+98 21 2243 2500

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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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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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Majid Valizadeh

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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