

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of Empagliflozin on blood glucose, BMI, HbA1c and insulin dose in patients with type 1 diabetes

Protocol summary

Study aim

Efficacy of empagliflozin as an insulin supplement in patients with type 1 diabetes

Design

The clinical trial was conducted in intervention group and control group, parallel, randomized, double-blinded groups

Settings and conduct

This study will be conducted as a pilot. In this study, 60 patients with type 1 diabetes were selected and randomly divided into two groups. The first group (30 people) will be given Empagliflozin at a dose of 10 mg per day and the second group (30 people) will be given placebo for 3 months. All patients continued their insulin. Parameters such as BMI, FBS, BS 2hpp, HbA1c and insulin consumption will be measured before and after drug and placebo administration. Patients are examined in terms of kidney function and acute and chronic complications of diabetes, and they will be withdrawn if there are complications. Patients will be given detailed training on blood sugar control and urine strips will be delivered to check urine ketones so that urine ketones can be measured daily.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Type 1 diabetes Age over 18 years and less than 30 years Able to measure blood sugar daily Be able to measure daily urine ketones HbA1C between 7.5% - 8.5% Exclusion Criteria: Kidney failure Active infection urinary infection pregnancy Cortone use

Intervention groups

Control group: The control group individuals will receive the placebo drug daily for 3 months. Intervention group: They receive 10 mg of empagliflozin daily for three months.

Main outcome variables

Hemoglobin A1c, Fasting Blood Sugar, 2 hour Post Prandial, Blood sugar, Body Mass Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130610013612N12**

Registration date: **2022-09-12, 1401/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-12, 1401/06/21**

Update count: **0**

Registration date

2022-09-12, 1401/06/21

Registrant information

Name

Farzad Najafipour

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7850

Email address

najafipourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Empagliflozin on blood glucose, BMI, HbA1c and insulin dose in patients with type 1 diabetes

Public title

Evaluation of the effect of Empagliflozin on blood glucose, BMI, HbA1c and insulin dose in patients with type 1 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type 1 diabetes Age over 18 years and less than 30 years Able to measure blood sugar daily Be able to measure daily urine ketones HbA1C between 7.5% - 8.5%

Exclusion criteria:

Kidney failure Active infection urinary infection pregnancy Cortone use

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified permuted block randomization will be applied to stratify participants into different stratum and blocks based on gender and probable confounders. Each block will be randomly allocated to the intervention or control groups. The sequence of the blocks will be prepared for each stratum Random Allocation Software (RAS). For each patient in a definite block, a matched person in terms of the aforementioned variables would be considered in that block. Participants and investigators will be blind to the trial group assignments until the end of the study and data analysis.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the main investigator and patients will be blind (empagliflozin or placebo) . The person responsible for preparing the supplement sachets (who is completely unrelated to the study) will be asked to assign a three digit code to each of the two (empagliflozin and placebo), and keep the codes for himself until the end of the study and data analyses.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Tabriz University of Medical Sciences

Street address

Ethics Committee, Tabriz University of Medical Sciences, Golgasht Street , Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2022-08-21, 1401/05/30

Ethics committee reference number

IR.TBZMED.REC.1401.442

Health conditions studied

1

Description of health condition studied

Diabetes type 1

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

Baseline and 3 months after the treatment

Method of measurement

Electrochemiluminescence Test

2

Description

Fasting Blood Sugar

Timepoint

Baseline and 3 months after the treatment

Method of measurement

Electrochemiluminescence Test

3

Description

2 hour Post Prandial

Timepoint

Baseline and 3 months after the treatment
Method of measurement
Electrochemiluminescence Test

4

Description
Body Mass Index
Timepoint
Baseline and 3 months after the treatment
Method of measurement
weight scale and stadiometer

Secondary outcomes

empty

Intervention groups

1

Description
Control group: the control group individuals will receive starch tablets which are completely identical in appearance to the supplement and will receive daily for 3 months.
Category
Placebo

2

Description
Intervention group: The supplement group will take one empagliflozin tablet (10 mg) made by Varian Farmed company for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Imam Reza Hospital
Full name of responsible person
Dr. Farzad Najfipour
Street address
Department of Endocrinology, Imam Reza Hospital, Daneshgah Square, Tabriz, East Azarbaijan
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 8939
Email
najafipourf@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
Vice chancellor for Research, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Grant name
30% grant for active university researchers
Grant code / Reference number
70431
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and Metabolism
Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
City
Tabriz

Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 8939
Email
najafipourf@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and Metabolism
Street address
Department of Endocrinology, Imam Reza Hospital,
Tabriz University of Medical Sciences, Golgasht
Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 8939
Email
najafipourf@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Farzad Najafipour
Position
Associate professor
Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology and Metabolism
Street address
Department of Endocrinology, Imam Reza Hospital,
Tabriz University of Medical Sciences, Golgasht
Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 8939
Email
najafipourf@tbzmed.ac.ir

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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared.
When the data will become available and for how long
Access starting 12 months after publication
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.
From where data/document is obtainable
The researchers (student and her supervisor)
What processes are involved for a request to access data/document
Request a document via email
Comments