

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessment of serum levels of Beta hydroxybutyrate, Glucagon, Cortisol and Insulin before and after one month treatment with Empagliflozin in comparison with Metformin in type 2 diabetic patients

Protocol summary

Study aim

Assessment of serum levels of Beta hydroxybutyrate, Glucagon, Cortisol and Insulin in type 2 diabetic patients before and after one month treatment with Empagliflozin in comparison with Metformin.

Design

This study is a randomized, single blinded trial with control and intervention parallel groups. Randomisation will be done in 50 type 2 diabetic patients, with the block randomisation method using the online creation of a randomisation list.

Settings and conduct

Type 2 diabetic patients who refer to Shahid Motahari and Shahid Faghihi clinics of Shiraz University of Medical Sciences will be allocated to intervention or control groups by blocked randomisation and will be followed for one month. In the intervention group Empagliflozin will be added to Metformin. The participants will be blind to their allocated group. In addition, the staff who collect data and assess outcomes are also blind to the groups of the participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: type 2 diabetic patients 30 year old or more, uncontrolled blood sugar after 3 months treatment with Metformin (Glycated hemoglobin (HbA1c) more than 7 to 9%). Exclusion criteria are: pregnant and lactating women, renal failure (Glomerular Filtration Rate (GFR) less than 45 milliliters per minute), previous history of diabetic ketoacidosis, previous history of amputation due to diabetes and consumption of drugs that affect the parameters of this study.

Intervention groups

Control group: diabetic patients who are treated with Metformin; Intervention group: diabetic patients who will receive Metformin and Empagliflozin

Main outcome variables

Beta hydroxybutyrate, Glucagon, Cortisol, Insulin,

Fasting blood sugar (FBS), Homeostatic Model Assessment for Insulin Resistance (HOMA-IR), Weight, Body Mass Index (BMI) Glycated hemoglobin (HbA1c)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210730052022N1**

Registration date: **2021-11-15, 1400/08/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-15, 1400/08/24**

Update count: **0**

Registration date

2021-11-15, 1400/08/24

Registrant information

Name

arash arya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 6403

Email address

arya91842@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of serum levels of Beta hydroxybutyrate, Glucagon, Cortisol and Insulin before and after one month treatment with Empagliflozin in comparison with Metformin in type 2 diabetic patients

Public title

The effect of Empagliflozin on Glucagon, Beta hydroxybutyrate and insulin levels in type 2 diabetic patients

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetic patients Thirty year old or more
Uncontrolled blood sugar after at least 3 months treatment with Metformin

Exclusion criteria:

Pregnant and lactating women Renal failure (Glomerular Filtration Rate (GFR) less than 45 milliliters per minute)
Previous history of diabetic ketoacidosis (DKA) Previous history of amputation due to diabetes Consumption of drugs that affect the parameters of study

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomisation In this study patients with type 2 diabetes who referred to our clinics will be randomized in to two groups according to block randomisation list with block size of 6. The control group will receive Metformin and the intervention group will receive Empagliflozin and Metformin. In this study the participants are unaware of the group assigned to them by the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

The main researcher will assign the patients to their groups based on the randomisation method which was considered for this study. The participants, the staff who collect data or assess the outcomes will be unaware of the allocated group of the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2021-07-19, 1400/04/28

Ethics committee reference number

IR.SUMS.MED.REC.1400.256

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Serum level of Beta hydroxybutyrate

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Colorimetric assay using Randox kit with autoanalyzer

2**Description**

Serum level of Glucagon

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Enzyme Linked Immunosorbent Assay (ELISA) method

3**Description**

Serum level of Cortisol

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Radioimmunoassay (RIA) method

4

Description

Serum level of Insulin

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Radioimmunoassay (RIA) method

Secondary outcomes

1

Description

Homeostatic Model Assessment of Insulin Resistance (HOMA-IR)

Timepoint

Before and then one month after treatment with Empagliflozin

Method of measurement

Calculation using blood sugar and Insulin levels in fasting state

2

Description

Weight

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Scale

3

Description

Body Mass Index (BMI)

Timepoint

Before starting and then after one month treatment with Empagliflozin

Method of measurement

Calculation using weight and height

4

Description

Fasting Blood Sugar (FBS)

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Colorimetric method with autoanalyzer

5

Description

Blood pressure

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

Sphygmomanometer

6

Description

Glycated Hemoglobin (HbA1c)

Timepoint

Before starting and then one month after treatment with Empagliflozin

Method of measurement

High-Performance Liquid Chromatography (HPLC)

Intervention groups

1

Description

Intervention group: patients with type 2 diabetes who received Metformin for at least three months but their HbA1c is greater than 7 to 9%. They will receive 10 miligram tablets of Empagliflozin (produced by Abidi Pharmaceuticals company) daily in addition to Metformin for one month.

Category

Treatment - Drugs

2

Description

Control group: patients with type 2 diabetes who have taken Metformin for at least three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari clinic

Full name of responsible person

Arash Arya

Street address

Shahid Motahari clinic, Namazi Square, Zand Blvd, Shiraz

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Zand Blvd, in front of Felestin Ave

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Web page address

<https://research.sums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Arash Arya

Position

Endocrinology fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Full name of responsible person

Arash Arya

Position

Endocrinology fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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