Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Empaglifozin 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 outc omes 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
۱۴۳۳۶ - 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 strarting 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-Perforrmance 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
City
Shiraz
Province
Fars
Postal code
7134814734
Phone
+98 71 3612 1000
Email
motahari@sums.ac.ir
Web page address

2

Recruitment center

Name of recruitment center
Shahid Faghihi clinic

Full name of responsible person
Arash Arya

Street address
Shahid Faghihi clinic, Zand Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3235 1087

Email
faghihisp@sums.ac.ir

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

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3212 2430

Email
vcrdep@sums.ac.ir

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

Street address
Namazi Square , Namazi hospital, Zand Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7193711351

Phone
+98 71 3228 6403

Fax

Email
arya91842@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fariba Karimi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Namazi Square , Namazi hospital, Zand Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7193711351

Phone
+98 71 3624 6096

Fax

Email
karimif2002@yahoo.com

Person responsible for updating data

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
Street address
Namazi Square , Namazi hospital, Zand Blvd, Shiraz
City
Shiraz
Province
Fars
Postal code
7193711351
Phone
+98 71 3228 6403
Fax
Email
arya91842@yahoo.com

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