

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of empagliflozin on the serum level of glycosylated hemoglobin in patients with type 2 diabetes

Protocol summary

Study aim

Determining the effect of empagliflozin glucose on the serum level of glycosylated hemoglobin in patients with type 2 diabetes

Design

Clinical trial with an intervention group

Settings and conduct

This study is conducted in Waliar Hospital, Birjand, South Khorasan Province. 45 diabetic patients living in the city of Birjand referring to the diabetes clinic and the specialized clinic of Waliar Birjand hospital in 1403 are included in the study.

Participants/Inclusion and exclusion criteria

Our study population will be diabetic patients living in the city of Birjand referring to the diabetes clinic and the specialized clinic of Waliar Hospital in Birjand in 1402. Inclusion criteria: patients with type 2 diabetes, having diabetes for at least 6 months, patients treated with oral medication, glycosylated hemoglobin below 10 and above 8, previous treatment of the patient with 2 grams of metformin and lack of appropriate treatment response, and exclusion criteria Study: Patients consuming minerals, vitamins or antioxidants or medicinal herbs, pregnant or lactating women, patients with heart failure, having chronic diseases such as rheumatology, thyroid problems, whether hypothyroid or hyperthyroid, patients receiving NPH insulin (aspartate, lispro) and glargine) and regular and patients with kidney failure, chronic kidney disease (CKD) (GFR > 30 ml/min), liver and patients undergoing treatment for gastrointestinal diseases.

Intervention groups

45 diabetic patients living in the city of Birjand referred to the diabetes clinic and specialized clinic of Waliar Hospital in Birjand in 1403.

Main outcome variables

Fasting blood sugar (FBS): Glycosylated hemoglobin (HbA1C): Blood sugar 2 hours after eating (2hbp)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N30**

Registration date: **2024-11-14, 1403/08/24**

Registration timing: **prospective**

Last update: **2024-11-14, 1403/08/24**

Update count: **0**

Registration date

2024-11-14, 1403/08/24

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empagliflozin on the serum level of glycosylated hemoglobin in patients with type 2 diabetes

Public title

Investigating the effect of empagliflozin on the serum level of glycosylated hemoglobin in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes Having diabetes for at least 6 months Patients treated with oral medication Glycosylated hemoglobin below 10 and above 8 Previous treatment of the patient with 2 grams of metformin and lack of adequate treatment response

Exclusion criteria:

Patients consuming minerals, vitamins or antioxidants or medicinal plants Pregnant or lactating women A patient with heart failure Having a chronic disease such as rheumatology diseases Thyroid problems, whether hypothyroid or hyperthyroid Patients receiving NPH insulin (aspartate, lispro and glargine) and regular Patients with kidney failure, chronic kidney disease (GFR > 30 ml/min), liver failure and patients undergoing treatment for gastrointestinal diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 45

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2024-10-28, 1403/08/07

Ethics committee reference number

IR.BUMS.REC.1403.265

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

In serum samples of patients using the Bionic company kit

2

Description

Glycosylated hemoglobin

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

In serum samples of patients using the Bionic company kit

3

Description

Fasting blood sugar 2 hours after eating

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

In serum samples of patients using the Bionic company kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The number of 45 diabetic patients living in Birjand city will refer to the diabetes clinic and specialized clinic of Valiasr Birjand hospital in 1403.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Birjand Hospital

Full name of responsible person

Dr Razieh Ayati

Street address

Valiasr Hospital Diabetes Clinic. Ghafari Blvd, Birjand, South Khorasan, Iran.

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Email

Valiasrhospital@bums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Masoud Yousefi

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Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand, South Khorasan, Iran.

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Shaghayesgh Aghasizadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

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Internal Medicine

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Person responsible for updating data

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Full name of responsible person

Zabihullah Mohaghegh

Position

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Latest degree

Bachelor

Other areas of specialty/work

General Practitioner

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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