Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

The effects of empagliflozin on neuropathy and retinopathy outcomes, renal function, and quality of life in patients with type 2 diabetes in Bojnurd

Protocol summary

Study aim

The effect of empagliflozin on renal, retinopathy, neuropathy outcomes, and quality of life in type 2 diabetics

Design

This study is a randomized double blind clinical trial study. Patients in the study were randomly divided into two groups receiving empagliflozin at 10 mg daily or placebo . Under special circumstances, the patient will receive emergency treatment. When the patient's hyperglycemia or hypoglycemia is uncontrollable, the patient is excluded. The allocation of patients to each of the study groups will be stratified randomly. According to the HbA1c index, patients are initially divided into two groups greater than 8.5 mg/dl and less than 8.5 mg/dl. Then, the required volume in each group is randomly assigned to each group. Randomization is done using a computer. The code of each intervention is kept confidential and given to the therapist by the clinic secretary to ensure the correct allocation is made randomly. The duration of treatment will be 24 weeks. At the beginning and end of the study, the target variables of the study will be examined. Patients will also be evaluated for side effects of the drug

Settings and conduct

The study population will be patients with type 2 diabetes referred to endocrinologist office in Bojnourd. In this study, the therapist, patients, and the individual analyzing the results are blinded to the allocation of patints into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients known for at least 6 months Exclusion criteria: eGFR less than 45, liver failure, type 1 diabetes, severe cardiovascular problems in the last three months, pregnancy and lactation.

Intervention groups

Case group: Empagliflozin recipient Control group: placebo recipient

Main outcome variables

Glycemic indexes, liver and kidney functions, retinopathy and neuropathy complications, pain score, and quality of life

General information

Reason for update

Adding a few other outcomes following the administration of empagliflozin (quality of life)

Acronym

IRCT registration information

IRCT registration number: **IRCT20191126045505N1**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **prospective**

Last update: **2023-07-10, 1402/04/19**
Update count: **2**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Habibe Sadat Shakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3222 8118

Email address

drhssh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of empagliflozin on neuropathy and retinopathy outcomes, renal function, and quality of life in patients with type 2 diabetes in Bojnurd

Public title
Effects of empagliflozin in diabetes treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetic patients who have been diagnosed for at least 6 months and treated at least with two anti-diabetic drugs. 7<HbA1c>10 BMI= Kg/m245
Exclusion criteria:
EGFR<45 Liver Failure Type1 diabetes History of ketosis History of frequent falls and recurrent infections Significant renal disease requiring dialysis Inappropriate drug use Serious medical conditions such as severe cardiovascular disease such as heart attack or stroke in the last three months Blood pressure above 180/110 mmHg Major surgery performed in the last 28 days Cancer treatment in the past 5 years Receiving systemic glucocorticoids Alcohol or substance abuse Pregnancy and lactation
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
patients will be allocated to each group stratified randomly. According to the HbA1c index, patients are first divided into<5.8 and>5.8. Then, the required volume in each group (50 people) is randomly selected from the category.Randomization is done using a computer. For the purpose of the random assignment correctly, the code of any intervention is kept confidential by the secretary of the clinic regardless the patients' condition. Then, these envelopes are sealed and is giving to the specialist who will assign each patient to one of the intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants and researchers (therapist) are not aware of the type of intervention for each patient.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee for Research of North Khorasan University of Medical Sciences
Street address
Central Building of North Khorasan University of Medical Sciences, Dolat Boulevard, Bojnourd
City
Bojnurd
Province
North Khorasan
Postal code
74877-94149
Approval date
2019-11-03, 1398/08/12
Ethics committee reference number
IR.NKUMS.REC.1398.096

Health conditions studied

1

Description of health condition studied
type II Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Evaluation of glycated hemoglobin or long-term blood sugar
Timepoint
Weeks 0 and 24
Method of measurement
Using the laboratory kit

2

Description
Fasting blood sugar measurement

Timepoint
Weeks 0 and 24
Method of measurement
Using the laboratory kit

3

Description
Measurement of glomerular filtration level for indirect evaluation of kidney status
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

4

Description
Measurement of urine albumin concentration
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

5

Description
Urine creatinine measurement
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

6

Description
Measurement of changes in urinary albumin / creatinine ratio
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

7

Description
Evaluation of aspartate aminotransferase level for evaluation of liver function
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

8

Description
Evaluation of alanine aminotransferase level for evaluation of liver function
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

9

Description
Measurement of blood alkaline phosphatase level for evaluation of hepatic function
Timepoint
weeks 0 and 24
Method of measurement
Using the laboratory kit

10

Description
Patient quality of life
Timepoint
Weeks 0 and 24
Method of measurement
DQOL questionnaire

11

Description
Retinopathy studies
Timepoint
Weeks 0 and 24
Method of measurement
Measurement of central macular thickness, corrected visual acuity, thickness of retinal and central subcutaneous tissue

12

Description
Neuropathy examinations
Timepoint
Weeks 0 and 24
Method of measurement
Pain score changes, EMG and NCV

Secondary outcomes

empty

Intervention groups

1

Description
The participants receiving placebo at a dose of 10 mg per day for three months (in the morning and with water) or placebo, in combination with the patient's previous medications, including metformin. , sulfonylurea and non-sulfonylurea (with the maximum tolerated dose or the maximum dose based on the drug label) will be allocated. Medicines prescribed to patients (empagliflozin tablets and placebo) are prepared in the form of tablets of the same shape. The drug is prepared in the exact same way as empagliflozin produced in Abidi factory and by the order of the same company (with the cooperation of the scientific representative of this company).
Category
Placebo

2

Description
Intervention group: The participants receiving empagliflozin at a dose of 10 mg per day for three months (in the morning and with water)in combination with the patient's previous medications, including metformin. , sulfonylurea and non-sulfonylurea (with the maximum tolerated dose or the maximum dose based on the drug label) will be allocated. Medicines prescribed to patients (placebo) are prepared in the form of tablets of the same shape. The drug is prepared in the exact same way as empagliflozin produced in Abidi factory and by the order of the same company (with the cooperation of the scientific representative of this company).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrinologist office in Bojnourd city

Full name of responsible person
Habibeh Sadat Shakeri

Street address
Research and Medical Center of Imam Hassan, North Khorasan, Pardis Town, Bojnourd, North Khorasan

City
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North Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Amir Amani

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North Khorasan University of Medical Sciences, Dolat Blv., Bojnurd, North Khorasan

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amani76@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences

Full name of responsible person
Habibeh Sadat Shakeri

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Educational, Research and Medical Center of Imam Hasan, Pardis town, Bojnurd, North khorasan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bojnourd University of Medical Sciences

Full name of responsible person
Habibeh Sadat Shakeri

Position
Associate professor

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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
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
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
At the end of the study and after the results are published, information about the study protocol, how to analyze the data, and the main outcomes are shared.

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
Researchers working in academia and in the industries

Under which criteria data/document could be used
Any analysis and use of the data and documentation submitted will be conditional with informing project executor and her consent.

From where data/document is obtainable
Refer to Dr. Habieh Sadat Shakeri, principal Executor, for the documentation. Email: drhssh@yahoo.com Affiliations: Faculty of Medicine, Bojnourd University of Medical Sciences

What processes are involved for a request to access data/document
The applicant should send an application to Dr. Habieh Sadat Shaker by email and she will respond as soon as possible after reviewing and consulting with other project members.

Comments
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