Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of empaglifluzine on the serum level of thyroid functional tests in prediabets and new-diagnosed diabetis

Protocol summary

Study aim
Determining the effect of empagliflozin on thyroid function tests

Design
Clinical trial without control group، without parallel group، non-randomized on 44 patients

Settings and conduct
All patients aged 18-65 who referred to Besat Clinic in Kerman with prediabet or type 2 diabetes who were newly diagnosed but are not being treated with any medication to control diabetes. All patients will go to a single laboratory for sampling at 8-10 in the morning and after filling the informed consent form، sampling will be done by an expert from the partner workshop of the plan for TSH، TT3، TT4، FT4، BUN، CR، FBS، HBA1c، TG، CHOL، LDL، HDL are done. Patients must be fasting for 12 hours before sampling، and blood pressure، height and weight of the patient will also be measured and recorded by the project partner. Patients are treated with empagliflozin 10 mg daily for three months, and at the end of the third month, TSH، TT3، TT4، FT4، TG، CHOL، LDL، HDL، BUN، CR، HBA1c، FBS tests in the same primary laboratory.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having diabetes mellitus 2 or prediabet 2- The level of HBA1c is at most 0.5-1% more than the target set for the patient 3- Not receiving medication to control blood sugar Exit criteria: 1- Suffering from type 1 diabetes 2- Suffering from thyroid dysfunction (hypothyroidism، hyperthyroidism) 3- Use of methimazole or levothyroxine 4- Use of insulin or diabetes control drugs 5- GFR<30 6- History of diabetic ketoacidosis or any underlying disease that predisposes a person to acidosis. 7- Liver failure 8-Patients who are treated with other drugs affecting the metabolism of thyroid hormones

Intervention groups
Administration of empagliflozin to prediabets and type 2 diabetes patients with normal thyroid function

Main outcome variables
TSH ،T3، free T4،total T4 after 3 months of empagliflozin consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090317001774N10**
Registration date: **2023-02-23, 1401/12/04**
Registration timing: **prospective**

Last update: **2023-02-23, 1401/12/04**
Update count: **0**

Registration date
2023-02-23, 1401/12/04

Registrant information

Name
Mojgan Sanjari

Name of organization / entity
Kerman University of Medical Science

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Iran (Islamic Republic of)

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+98 34 1322 2506

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msanjari@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-25, 1402/01/05

Expected recruitment end date
2023-04-25, 1402/02/05

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of empaglifluzine on the serum level of thyroid functional tests in prediabets and new-diagnosed diabetis

Public title

Empaglifluzin effect on thyroid function tests

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetes type 2 or prediabet The level of HBA1c، 0.5-1% more than the target set for the patient Not receiving medication to control diabetes

Exclusion criteria:

Diabetes type 1 Hypo or hyperthyroidism Consumption of levothyroxine or methimazole Use of insulin or diabetes control drugs (biguanides، sulfonylureas، thiazolideones، SGLT2- inhibitors، GLP-1 receptor agonists، bromocriptine، cholestyramine، Dapaglifluzin GFR<30 A history of diabetic ketoacidosis or any underlying disease that predisposes a person to acidosis. History of liver failure Patients who are treated with other drugs affecting the metabolism of thyroid hormones (Amiodarone، Lithium، Androgen، Estrogen)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Not randomized

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

Research Ethics Committees of Kerman University of Medical Sciences

Street address

Imam Khomeini Highway

City

kerman

Province

Kerman

Postal code

7616913355

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.KMU.AH.REC.1401.224

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

Serum thyroid stimulating hormone level

Timepoint

Before starting the study and after three months taking of empagliflozin

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Serum T4 level

Timepoint

Before starting the study and after three months taking of empagliflozin

Method of measurement

Blood sampling

Intervention groups

1

Description

Intervention group: patients with prediabetes and type 2 diabetes under treatment for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Clinic
Full name of responsible person
Dr. Mojgan Sanjari
Street address
Somayeh Crossroads (Tahmasebabad)
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reza MalekpourAfshar
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Mojgan Sanjari
Position
professor
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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
Not applicable
Data Dictionary
Not applicable