

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Evaluation of the effect of empagliflozin on the serum level of thyroid functional tests in prediabetics and new-diagnosed diabetes

#### 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 prediabetes 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 prediabetes 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 prediabetics 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1322 2506

##### Email address

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 empaglifuzine on the serum level of thyroid functional tests in prediabetes and new-diagnosed diabetes

**Public title**  
Empaglifuzin 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, thiazolidiones, SGLT2- inhibitors, GLP-1 receptor agonists, bromocriptine, cholestyramine, Dapaglifuzin 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)

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3226 8740

**Email**

msanjari@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Reza MalekpourAfshar

**Street address**

Haft-Bagh Highway

**City**

Kerman

**Province**

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**Phone**

+98 34 3226 3855

**Email**

malekpour@kmu.ac.ir

**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

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Endocrinology

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

professor

**Latest degree**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mojgan Sanjari

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work****Street address**

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**Email**

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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