Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of standard treatment of three drugs empagliflozin + linagliptin + metformin (trijardi xr) on BMI, lipid profile, vitamin D in type 2 diabetic patients resistant to two drugs metformin + sitagliptin, referring to the endocrinology clinic

Protocol summary

Study aim

Determining the effect of standard treatment of three drugs empagliflozin + linagliptin + metformin (trijardi xr) on BMI, lipid profile, vitamin D in type 2 diabetic patients resistant to two drugs metformin + sitagliptin

Design

In this study, the randomization process of 28 type 2 diabetic patients was not done in treatment groups, but they received the usual standard treatment. The process of randomization, random allocation of samples to groups and blinding is not done. This study does not measure the effectiveness, but shows a general review of the intervention in relation to the investigated variables.

Settings and conduct

A semi-experimental study in diabetic patients referred to the endocrinology clinic of Ganjavian Dezful Hospital

Participants/Inclusion and exclusion criteria

Conditions of entry: Patients with diabetes resistant to treatment with gliclazide or metformin, age over 18 years with BMI ≤ ≥25, HBA1C> ≤10.5, FBS<250, GFR>30, no change in treatment ≥12 weeks before the study and under treatment with metformin + sitagliptin combination drug. Exclusion conditions: GFR<30, history of recurrent urinary tract infections, history of frequent urination, BMI<25, ACS, STROKE or TIA in the past three months, bariatric surgery in the past two years, treatment with anti-obesity drugs in the past 3 months, prone to lactic acidosis or pancreatitis, type 2 diabetes One, pregnancy.

Intervention groups

At the beginning of the study, patients' FBS, HBA1C, BMI, lipid profile and vitamin D are evaluated. After the patients entered the present study, they were treated with the combined drug of empagliflozin 12.5 mg + linagliptin 2.5 mg + metformin 1000 mg for 3 months. Then, at the end of the study, by sampling the patient's blood, the mentioned variables are evaluated.

Main outcome variables

FBS; HbA1c; Lipid profile; Vitamin D; BMI.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240215061021N1**
Registration date: **2024-03-10, 1402/12/20**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-10, 1402/12/20**
Update count: **0**

Registration date

2024-03-10, 1402/12/20

Registrant information

Name

Nasim Shirinsahrae

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 4226 0683

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of standard treatment of three drugs empagliflozin + linagliptin + metformin (trijardi xr) on BMI, lipid profile, vitamin D in type 2 diabetic patients resistant to two drugs metformin + sitagliptin, referring to the endocrinology clinic

Public title

Investigating the effect of standard treatment of three drugs empagliflozin + linagliptin + metformin (trijardi xr) on controlling blood sugar, weight, vitamin D and lipid profile of patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

bmi range between 25 and 45 Patients with diabetes resistant to treatment with gliclazide or metformin Age more than 18 years Hba1c should be between 7 and 10.5 Fbs less than 250 Gfr more than 30 No change in treatment ≥12 weeks before the study be treated with metformin + sitagliptin combination drug

Exclusion criteria:

GFR<30 History of recurrent urinary tract infections History of frequent urination Bmi less than 25 ACS, STROKe or TIA in the last three months Bariatric surgery at least two years ago Be susceptible to lactic acidosis or pancreatitis Dm1 Pregnancy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **28**

More than 1 sample in each individual

Number of samples in each individual: **2**

Before and after treatment

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 Dezful University of Medical Sciences

Street address

Azadegan St., Dezful University of Medical Sciences

City

Dezful

Province

Khouzestan

Postal code

6461669969

Approval date

2024-02-05, 1402/11/16

Ethics committee reference number

IR.DUMS.REC.1402.061

Health conditions studied

1

Description of health condition studied

type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

before the start of the study and three months after the start of treatment

Method of measurement

Measurement through variable measurement by laboratory diagnostic kit

2

Description

HbA1c

Timepoint

before the start of the study and three months after the start of treatment

Method of measurement

Measurement through variable measurement by laboratory diagnostic kit

Secondary outcomes

1

Description
Lipid profile
Timepoint
before the start of the study and three months after the start of treatment
Method of measurement
Measurement through variable measurement by laboratory diagnostic kit

2

Description
Vitamin D
Timepoint
before the start of the study and three months after the start of treatment
Method of measurement
Measurement through variable measurement by laboratory diagnostic kit

3

Description
BMI
Timepoint
before the start of the study and three months after the start of treatment
Method of measurement
How to calculate BMI: Weight (kg) / height squared (m2) BMI

Intervention groups

1

Description
At the beginning of the study, patients' FBS, HBA1C, BMI, lipid profile and vitamin D are evaluated. After the patients entered the present study, they were treated with the combined drug of empagliflozin 12.5 mg + linagliptin 2.5 mg + metformin 1000 mg for 3 months. Then, at the end of the study, by sampling the patient's blood, FBS, HBA1C, lipid profile, vitamin D and BMI variables are evaluated again through calculation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Clinic of Ganjavian Dezful Hospital
Full name of responsible person
Dr. Hamid Karimi
Street address
Azadegan St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dezfoul University of Medical Sciences
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Dr. Mohammad Amin Behmanesh
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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
Dezfoul 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
Dezfoul University of Medical Sciences
Full name of responsible person
Nasim Shirinsahrae
Position
Internal resident
Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only the results obtained from the laboratory tests can and will be published scientifically. Personal information of individuals is not published based on confidentiality rules.
When the data will become available and for how long
6 months after the publication of the article
To whom data/document is available
Academic and scientific researchers
Under which criteria data/document could be used
If the present research project is continued in future studies by other university researchers, the results of data analysis will be provided to them.
From where data/document is obtainable
Dr. Nasim Shirinsahraee Email: drn.shirin1398@gmail.com
What processes are involved for a request to access data/document
Submission of an official letter from the research vice-chancellor of the university or research center with the final approval of the ministers to the vice-chancellor of education, research and technology of Dezful University of Medical Sciences. The time required to submit the requested document is 1 month.
Comments