Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of therapeutic effect of Empagliflozin (Gloripa) and Sitagliptin (Ziptin) on uncontrolled type 2 Diabetic Patients

Protocol summary

Study aim
Comparison of the effects of adding Empagliflozin and Sitagliptin on improving glycemic control in patients with uncontrolled type 2 diabetes

Design
Two arm,parallel group, randomized trial, and double-blind

Settings and conduct
After recording all the demographic information of patients, including name, age, sex, ..., patients were divided into 2 groups of 64, the first group receiving 100 mg of Cytaglibetin daily, the second group receiving 10 mg of Empagliflozin daily simultaneously with Doses of previous medications and receiving diet and exercise counseling will be divided into three months of treatment, and patients will be studied for 3 months, and the dose of patients' medications will remain constant during these 3 months. It is a drug and this difference will not interfere with the study.) Patients receive periodic visits every month and at each monthly visit, weight is measured by a digital scale with an accuracy of 0.1 kg, height by a bar meter, and standing when the heel The patient's shoulders and shoulders are attached to the wall, and blood pressure is measured by a Richter mercury sphygmomanometer with a suitable arm cuff. Measurements are made by a single person and body mass index will be calculated with the relevant formula. At the end of the third month, venous blood sampling will be performed in patients with fasting conditions and the parameters of FBS, HbA1C, triglyceride, cholesterol, and LDL (measured with BT3000 and Pars test kits) and their weight and blood pressure and mass index Bodies will be evaluated between study groups.

Participants/Inclusion and exclusion criteria
Patients with type 2 diabetes, age between 18 and 80, (HbA1c between 6.5-9) during the last six months, taking metformin±sulfonylurea(mostly gliclazide)±pioglitazone

Intervention groups
group A Gloripa (10 mg)؛ group B Zeptin (100 mg)

Main outcome variables
lipid profile؛Bp؛FBS؛HbA1c؛BMI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200810048355N1**
Registration date: **2021-06-13, 1400/03/23**
Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**
Update count: **0**

Registration date
2021-06-13, 1400/03/23

Registrant information

Name
Fateme Salehi poor

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3446 2072

Email address
ftmslhp@smd.iaun.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effect of Empagliflozin (Gloripa) and Sitagliptin (Ziptin) on uncontrolled type 2 Diabetic Patients

Public title
Comparison of therapeutic effect of Empagliflozin (Gloripa) and Sitagliptin (Ziptin) on type 2 Diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes Age between 18 and 80 (HbA1c between 6.5-9) during the last 6 months Metformin ± Sulfonylurea (often gliclazide) ± Pioglitazone
Exclusion criteria:
GFR<45 Hepatic Failure Ill and toxic patients DM Type 1 Dissatisfaction with continued cooperation Insulin Use GLP-1 agonists

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will perform by a computer-based dynamic allocation method.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants and the person who will analyze the data collected during the study will be unaware of the allocation of patients to the intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Ethics Committee
Street address
Daneshgah Blvd, Basij Blvd
City
Falavarjan
Province
Isfehan
Postal code
۱۵۵/۸۴۵۱۵
Approval date
2021-05-03, 1400/02/13
Ethics committee reference number
IR.IAU.FALA.REC.1400.004

Health conditions studied

1

Description of health condition studied
Diabetes Melitus Type tow
ICD-10 code
5A11
ICD-10 code description
Diabetes mellitus type 2 (formerly noninsulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes) is a metabolic disorder that is characterised by high blood glucose in the context of insulin resistance and relative insulin deficiency.

Primary outcomes

1

Description
FBS
Timepoint
At the beginning of the study and 3 months after treatment
Method of measurement
Blood sample

2

Description
HbA1C
Timepoint
At the beginning of the study and 3 months after treatment
Method of measurement
Blood sample

3

Description
Blood pressure
Timepoint
At the beginning of the study and 3 months after treatment
Method of measurement

Mercury barometer

4

Description
Lipid profile
Timepoint
At the beginning of the study and 3 months after treatment
Method of measurement
Blood sample

5

Description
Body mass index
Timepoint
At the beginning of the study and 3 months after treatment
Method of measurement
Height and Weight measurment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group receives 100 mg of Cytagliptin daily at the same time as the previous dose of metformin for 3 months.
Category
Treatment - Drugs

2

Description
Intervention group: The second group receives 10 mg daily of Empaglyphosine at the same time as the previous dose of metformin for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Ali Shariati Hospital
Full name of responsible person
Parichehr Vahabi
Street address
first Tajaldin Alley, Chahar-Bagh E bala Ave
City
Isfahan
Province
Isfehan
Postal code
81737 45384
Phone
+98 31 3627 2001
Email
pari.vahabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Islamic Aazad University, Najafabad branch
Full name of responsible person
Madi Rafie
Street address
Daneshgah Blvd, Najafabad Town
City
Najafabad
Province
Isfehan
Postal code
۸۵۱۴۱۴۳۱۳۱
Phone
+98 31 4229 2929
Email
info @ iaun.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Islamic Aazad University, Najafabad branch
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
Islamic Azad University
Full name of responsible person
Parichehr Vahabi Anaraki MD
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinologist
Street address

Daneshgah Blvd, Najafabad Town

City
Najafabad

Province
Isfehan

Postal code
۸۵۱۴۱۴۳۱۳۱

Phone
+98 31 4229 2929

Email
pari.vahabi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fatemeh Salehi pour

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Daneshgah Blvd, Najafabd Town

City
Najafabad

Province
Isfehan

Postal code
۸۵۱۴۱۴۳۱۳۱

Phone
+98 31 4229 1016

Email
fatemesalehi1996.fs@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fatemeh Salehi pour

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Daneshgah Blvd, Najafabd Town

City
Najafabad

Province
Isfehan

Postal code
۸۵۱۴۱۴۳۱۳۱

Phone
+98 31 4229 1016

Email
fatemesalehi1996.fs@gmail.com

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
Not applicable

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