Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of sitagliptin on total daily insulin dose, glycemic index, and hypoglycemic attacks in patients with type 1 diabetes

Protocol summary

Study aim
Determining and comparing the effect of sitagliptin on total daily insulin dose, glycemic index, and hypoglycemic attacks

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 90 patients

Settings and conduct
In this randomized triple-blind clinical trial study, 90 patients with type 1 diabetes referred to Isfahan Endocrine Research Center (Sedigheh Tahereh) will be included in the study and randomly divided into 2 groups. The first group receives 100 mg of sitagliptin and the second group receives 100 mg of placebo daily for up to 3 months. Then their total daily insulin dose, blood sugar and hypoglycemic attacks will be evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria include having type 1 diabetes treated with insulin, which takes less than 5 years to diagnose, having kidney failure (GFR> 50), age range between 18 and 60 years. and consent to participate in the study. The exclusion criteria are pregnancy, having a history of sitagliptin sensitivity, having a history of sitagliptin use in the last 6 months, and body mass index (BMI) less than 18 kg/m2.

Intervention groups
Intervention group: Patients in this group will receive 100 mg of sitagliptin in two doses of 50 mg daily for three months. Control group: Patients in this group will receive the placebo in two doses of 50 mg daily for three months.

Main outcome variables
Total insulin dose; Blood sugar; Hypoglycemic attacks

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20080902001181N3**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **prospective**

Last update: **2021-03-08, 1399/12/18**
Update count: **0**

Registration date
2021-03-08, 1399/12/18

Registrant information
Name
Mansour Siavash
Name of organization / entity
Isfahan Endocrine and Metabolism Research Center
Country
Iran (Islamic Republic of)
Phone
+98 31 1222 0998
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siavash@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-03-20, 1399/12/30
Expected recruitment end date
2021-07-21, 1400/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of sitagliptin on total daily insulin dose, glycemic index, and hypoglycemic attacks in patients with type 1 diabetes

Public title
The effect of sitagliptin on total daily insulin dose, glycemic index and hypoglycemic attacks
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having type 1 diabetes treated with insulin, which takes less than 5 years to diagnose. Kidney failure (GFR> 50) Age range between 18 and 60 years Consent to participate in the study
Exclusion criteria:
Pregnancy Having a history of sitagliptin sensitivity Having a history of sitagliptin use in the last 6 months Body mass index (BMI) less than 18 kg/m2
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
En In this study, 90 eligible couples will be simple randomly selected. Then random numbers are created by computer software "Random Allocation" and are automatically divided into two parts. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to a patient and therefore they will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, two drugs "sitagliptin " and "placebo" were prepared by a pharmacist with similar shape, color, smell and placed in coded packages, and provided to the researcher. He/She also provides it to the patient without knowing the type of each drug. Also, the patient, the person recording the patient's clinical information, and the statistical analyst will not be aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-01-22, 1399/11/03
Ethics committee reference number
IR.MUI.MED.REC.1399.974

Health conditions studied

1

Description of health condition studied
Type 1 diabetes mellitus
ICD-10 code
E10.9
ICD-10 code description
Type 1 diabetes mellitus without complications

Primary outcomes

1

Description
Daily insulin dose
Timepoint
Before and after the intervention
Method of measurement
Daily registration

2

Description
Blood sugar
Timepoint
Before and after the intervention
Method of measurement
Using a glucometer device

3

Description
Hypoglycemic attacks
Timepoint
Before and after the intervention
Method of measurement
Number of occurrences (view)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Patients in this group will receive placebo in two doses of 50 mg daily for three months.
Category
Placebo

2

Description
Intervention group: Patients in this group will receive 100 mg of cytagliptin in two doses of 50 mg daily for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine Research Center (Sedigheh Tahereh)
Full name of responsible person
Mansour Siavash
Street address
Sedigheh Tahereh Center, Khorram Street, Jomhuri Eslami Square.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

Mansour Siavash

Position
Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position
Non-faculty physician

Latest degree
Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available