

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Sitagliptin on Plasma Metabolic Factors, Cognitive Activities, Renal and Pancreatic Functions in Type 2 Diabetic Patients of Semnan city

Protocol summary

Study aim

Determining the effects of sitagliptin on inflammatory factors, renal and pancreatic function and cognitive activity in type 2 diabetics.

Design

A double-blind clinical trial with a parallel control group on 60 type 2 diabetic patients who will be randomly assigned to two groups. The two groups of type 2 diabetics will include the control group (those treated with metformin alone) and the intervention group (those treated with metformin and sitagliptin). Medications for both groups of patients are prescribed by the treating physician.

Settings and conduct

This study will be performed in medical centers of Semnan University of Medical Sciences. Blood and urine samples will be taken from all patients at the beginning and end of the study. Treatment of both groups will be done under the supervision of the treating physician. The patient, the patient's clinical caregiver, and the analyzer of the final results will be unaware of the grouping and allocation of drugs. But the treating physician and project manager will be aware of the medications and groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All type 2 diabetic patients; Having the informed consent; between 35 and 65 years; Healthy physical conditions; No history of taking DPP-4 inhibitors; Not being pregnant for women Exclusion criteria: history of malignancy, AIDS, hepatitis; acute psychologic diseases; Severe kidney disorder and cardiovascular problems.

Intervention groups

Type 2 diabetic patients treated with metformin alone (as control group) or metformin + sitagliptin (as intervention group)

Main outcome variables

Blood sugar; LDL; triglycerides; urine creatinine;

peripheral insulin sensitivity; inflammatory cytokines; memory; learning.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191209045671N1**

Registration date: **2020-11-12, 1399/08/22**

Registration timing: **prospective**

Last update: **2020-11-12, 1399/08/22**

Update count: **0**

Registration date

2020-11-12, 1399/08/22

Registrant information

Name

Habib Yaribeygi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4170

Email address

habib.yari@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Sitagliptin on Plasma Metabolic Factors, Cognitive Activities, Renal and Pancreatic Functions in Type 2 Diabetic Patients of Semnan city

Public title
The Effects of Sitagliptin on Type 2 Diabetic Patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes mellitus Healthy physical conditions No history of taking DPP-4 inhibitors Not being pregnant for women informed consent to participate in the study
Exclusion criteria:
A history of malignancy or diseases such as AIDS or hepatitis A history of acute psychological diseases Severe renal dysfunction cardiovascular disorders

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participating patient , the clinical caregiver (who is a nurse), and the epidemiologist who analyzing the final results are blind. But the treating physician and plan supervisor are aware of medications and groups.

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences
Street address
Basij Boulvared
City
Semnan
Province
Semnan
Postal code
35147-99442
Approval date
2020-09-22, 1399/07/01
Ethics committee reference number
IR.SEMUMS.REC.1399.186

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Decreased fasting blood glucose
Timepoint
Before and after the intervention
Method of measurement
Biochemical-laboratory method

2

Description
Improvement of plasma lipid profiles
Timepoint
Before and after the intervention
Method of measurement
Biochemical-laboratory method

3

Description
Improvement of cognitive functions
Timepoint
Before and after the intervention
Method of measurement
wechsler tool

4

Description
improvement in renal function

Timepoint

Before and after the intervention

Method of measurement

Biochemical-laboratory method

5**Description**

improve in pancreatic efficiency

Timepoint

Before and after the intervention

Method of measurement

Biochemical-laboratory method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Type 2 diabetic patients treated with metformin + DPP-4 inhibitor (Sitagliptin). These patients will be selected from the people referring to Semnan Diabetes Clinic and will take the desired drug orally for 90 days with a dose of 100 mg of sitagliptin and 2000 mg of metformin. This medication will be performed with a drug made by Abidi Pharmaceutical Company and under the supervision of the treating physician.

Category

Treatment - Drugs

2**Description**

Control group: Type 2 diabetic patients treated with metformin. These patients will be selected from the people referring to the Diabetes Clinic of Semnan and will take the desired drug orally for 90 days at a dose of 2000 mg of metformin. This medication will be performed with a drug made by Abidi Pharmaceutical Company and under the supervision of the treating physician.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar Hospital Diabetes Clinic

Full name of responsible person

Habib Yaribeygi

Street address

Basij

City

Semnan

Province

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Postal code

3519899951

Phone

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Email

kosarhos@semums.ac.ir

Web page address

<https://kosarhos.semums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Abidi pharmacy

Full name of responsible person

Dr. Seyed Amir Razavian Ardehali

Street address

8 km of Karaj special road, Dr. Obidi Boulevard

City

Tehran

Province

Tehran

Postal code

۷۶۳۶۳ - ۱۳۸۹۷

Phone

+98 21 4450 4787

Email

dr.soorena@gmail.com

Web page address

<https://abidipharma.com/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Abidi pharmacy

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Habib Yaribeygi

Position

Assistant professor

Latest degree

Ph.D.
Other areas of specialty/work
Physiology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
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Person responsible for updating data

Contact

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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

it has no ethical approve.

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

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 part of the data will be published in the form of a project report and article.

When the data will become available and for how long

Raw data will not be published. But the final results will be published in the form of reports and articles about 6 months after the end of the project.

To whom data/document is available

Everyone can read the final report and the resulting article.

Under which criteria data/document could be used

Only for writing the final report and article

From where data/document is obtainable

Physiology Research Center of Semnan University of Medical Sciences

What processes are involved for a request to access data/document

Raw data will not be published (due to ethical issues)

Comments