

# 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**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3343 7821

**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  
**Full name of responsible person**  
Habib Yaribeygi  
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Assistant professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
Majid Mirmohammadkhani  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
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majidmirmohammadkhani@yahoo.com

## 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