

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effects of atorvastatin consumption on blood levels of sortilin, blood sugar and lipid indices in patients with type 2 diabetes

#### Protocol summary

##### Study aim

Determining the effects of atorvastatin consumption on blood levels of sortilin, blood sugar and lipid indices in patients with type 2 diabetes

##### Design

This research is based on 60 people, and it will be conducted in three groups: These individuals were selected using a simple random method. Patients with type 2 diabetes will receive atorvastatin 40 mg/day for 3 months, and samples will be taken before and after three months of treatment. Healthy people will be sampled in one step, and then the desired variables will be measured.

##### Settings and conduct

Blood sugar and blood lipid indicators of patients and healthy individuals will be measured in the Shafai Babol laboratory. Serum, sortilin, and insulin levels will be measured using sandwich ELISA in the biochemistry laboratory of the Faculty of Medicine of Kerman University of Medical Sciences. Using serum glucose and insulin concentrations, the HOMA.IR index will be calculated in diabetic patients and healthy individuals.

##### Participants/Inclusion and exclusion criteria

The statistical population of this research includes patients with type 2 diabetes mellitus who are referred to an endocrinologist (the main collaborator of this project) and healthy (normal) people who are referred to the Shafai Pathology and Medical Diagnosis Laboratory in Babol city under the supervision of an endocrinology specialist. Pregnant women and people with a history of cancer or heart attack in the last 6 months were not included in the study.

##### Intervention groups

Patients with type 2 diabetes before and after treatment with atorvastatin 40 mg/day. Control group are healthy without complications and have no history of special diseases.

##### Main outcome variables

The effect of atorvastatin on sortilin and blood sugar and

lipid indices and the relationship between these factors in patients with type 2 diabetes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231122060137N1**

Registration date: **2023-12-12, 1402/09/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-12, 1402/09/21**

Update count: **0**

##### Registration date

2023-12-12, 1402/09/21

##### Registrant information

##### Name

Ali Nosrati andevari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 4425 3555

##### Email address

nosrati.ali70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-31, 1402/08/09

##### Expected recruitment end date

2024-04-29, 1403/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effects of atorvastatin consumption on blood levels of sortilin, blood sugar and lipid indices in patients with type 2 diabetes

**Public title**

The effects of atorvastatin consumption in patients with type 2 diabetes

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Type 2 diabetic patients have not used statin family drugs before treatment. Healthy people should visit the laboratory for a routine checkup Taking atorvastatin 40 mg/day for patients with type 2 diabetes who need treatment with this drug. Diabetic patients have diabetes for at least 2 years. Not received insulin in patients with type 2 diabetes and healthy people. Use of hypoglycemic drugs in patients with type 2 diabetes

**Exclusion criteria:**

Women who are pregnant or breastfeeding People who have an active infection or hepatitis B, hepatitis C, HIV, or tuberculosis History of any cancer Heart attack in the last 6 months or peripheral coronary artery disease Smoking and alcohol use Women who use contraceptives Indigestion and chronic diarrhea, failure of important organs, such as liver, lung, kidney, and brain, as well as anemia and diabetic nephropathy

**Age**

From **19 years** old to **69 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sampling method is a simple random method. In this way, people in the community have an equal chance of being elected. Each element of the desired statistical population has an equal chance of being selected. In this method, the required people are randomly selected from the statistical population list prepared for this purpose. According to the law of probability, the selected people should have the same characteristics as those of the society from which they were selected.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics committees of Kerman University of Medical Sciences

**Street address**

Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipur Medical Education Center

**City**

Kerman

**Province**

Mazandaran

**Postal code**

7616913355

**Approval date**

2023-10-30, 1402/08/08

**Ethics committee reference number**

IR.KMU.REC.1402.299

**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**

The blood level of sortilin

**Timepoint**

The mesearment of blood level of sortilin before treatment with atorvastatin and three months after treatment with it

**Method of measurement**

ELISA method using ELISA reader

**2****Description**

The levels of blood sugar indices

**Timepoint**

The mesearment of blood sugar indices before treatment with atorvastatin and three months after treatment with it

**Method of measurement**

Photometric method using autoanalyzer

### 3

#### **Description**

The levels of blood lipid indices

#### **Timepoint**

The mesearment of blood lipid indices before treatment with atorvastatin and three months after treatment with it

#### **Method of measurement**

Photometric method using autoanalyzer

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group 1: Patients with type 2 diabetes mellitus before treatment with atorvastatin 40 mg, these diabetic patients have not received atorvastatin so far, samples will be taken from them before treatment with atorvastatin 40 mg per day.

#### **Category**

Treatment - Drugs

#### 2

#### **Description**

Intervention group 2: Patients with type 2 diabetes mellitus after treatment with atorvastatin 40 mg. Patients take this medicine orally for three months

#### **Category**

Treatment - Drugs

#### 3

#### **Description**

Control group: Healthy people who do not have any diseases and do not take atorvastatin

#### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rouhani Hospital

##### **Full name of responsible person**

Neda Meftah

##### **Street address**

Kargar Street, University Square, Ganj Afrooz Street, Ayatollah Rouhani Hospital

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

47176-47745

#### **Phone**

+98 11 2229 5915

#### **Fax**

#### **Email**

info@mubabol.ac.ir

#### **Web page address**

http://rohani.mubabol.ac.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Abedin Iranpour

##### **Street address**

Samiya Crossroads (Tahmasababad) at the beginning of Ibn Sina Street, Research and Technology Office

##### **City**

Kerman

##### **Province**

Kerman

##### **Postal code**

0000000000

##### **Phone**

+98 34 3226 3719

##### **Email**

iranpourabedin89@gmail.com

##### **Web page address**

https://vresearch.kmu.ac.ir/fa

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Ali Nosrati Andevari

##### **Position**

phd student of clinical biochemistry

##### **Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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

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**Full name of responsible person**

Ali Nosrati Andevari

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phd student of Clinical Biochemistry

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**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

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**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**

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