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 cityunder 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
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47176-47745
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+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
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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
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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