Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effect of Atorvastatin administration time in the morning and evening on lipid profile in patients with type 2 diabetes

Protocol summary

Study aim
Evaluation of the effect of Atorvastatin administration time in the morning and evening on lipid profile in patients with type 2 diabetes referred to Ayatollah Rouhani Hospital

Design
This study is a clinical trial with a control group, with parallel groups, blinded assessor, randomized on 76 patients who were divided into two groups(atorvastatin prescription in the morning and atorvastatin prescription in the evening) are divided. Randomization by method permuted block design will be done using the website www.sealedenvelope.com.

Settings and conduct
All patients with type 2 diabetes referred to endocrine clinic of Ayatollah Rouhani Hospital who have an indication for receiving statin. Demographic information of patients will be collected in a checklist. After obtaining informed consent, the samples will be divided into two groups (atorvastatin administration in the morning and atorvastatin administration in the evening).Due to the nature of the treatment, in which the time of use is different, it is not possible to blind the patients.The person who is blind during the study is the assessor. After 12 hours of fasting, 5 cc of volunteers' blood is taken in the laboratory of Ayatollah Rouhani Hospital and the middle of lipids is measured by Pars Azmoon kit. After 4 weeks, lipid profiles will be measured again in the same laboratory and with the same measurement kit. Blood lipid levels will be recorded in the checklist.

Participants/Inclusion and exclusion criteria
Inclusion criteria : any diabetic patient over the age of 40 years Exclusion criteria : People with renal failure Cancer patients People who have used lipid-lowering drugs before

Intervention groups
The first group will be prescribed atorvastatin in the morning and the second group will be prescribed atorvastatin in the evening.

Main outcome variables
Comparison of change in blood lipid levels ; complications in both groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211211053359N1**
Registration date: **2022-09-26, 1401/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-26, 1401/07/04**
Update count: **0**

Registration date
2022-09-26, 1401/07/04

Registrant information

Name
Sepide Tavanaeifard

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-21, 1401/06/30

Expected recruitment end date
2022-11-20, 1401/08/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Atorvastatin administration time in the morning and evening on lipid profile in patients with type 2 diabetes

Public title

Evaluation of the effect of Atorvastatin in diabetic type 2 patients in the morning and evening

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Any diabetic patient over the age of 40

Exclusion criteria:

People with renal failure Patient with cancer People who have used lipid lowering drugs before

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by permuted block design. The size of the blocks is 4.In each block equal number of intervention (Administer medicine in the morning) and control (Administer medicine in the evening) are placed. Sequence production for randomization will be done by a statistician and using the www.sealedenvelope.com website. Envelopes of the same shape will be prepared and in closed envelopes, the time of receiving the medicine (morning / evening) is specified, the order of these envelopes will be determined using random blocks and through the www.sealedenvelope.com website. To hide the treatment process, envelopes of the same shape are prepared according to the number of people to be studied. Three-digit codes are written on the envelopes. After each person enters the study, to allocate his treatment time, one of these envelopes (in a specific order) is given to that person by the secretary and the code on the envelope is recorded on the patient's file. At the end of the study, the codes will be reopened.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blindness Due to the nature of treatment in which the time of use is different (For some patients it will be prescribed in the morning and for others in the evening) blinding patients is not possible. Due to the process and method of randomization ,The person who will be blind during the study is the assessor , the assessor does not know the time of drug administration.. Therefore, this study is out come assessor blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of babol University of Medical Sciences

Street address

Ganjafrooz St., University Square., Babol Town., Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2022-02-06, 1400/11/17

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.176

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of Atorvastatin administration time in the morning and evening on lipid profile in patients with type 2 diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood levels of lipid profiles

Timepoint

At the beginning of the study and after 4 weeks

Method of measurement

Blood lipid profile (TG, HDL, LDL)

Secondary outcomes

1

Description
Gastrointestinal complication
Timepoint
At the beginning of the administration of the drug on a daily basis
Method of measurement
Gastrointestinal complications will be recorded by the patients in the corresponding checklist on a daily basis.

2

Description
Musculoskeletal complications
Timepoint
At the beginning of the administration of the drug on a daily basis
Method of measurement
Musculoskeletal complications will be recorded by the patients in the corresponding checklist on a daily basis.

Intervention groups

1

Description
Intervention group:In this randomized clinical trial, participants will be randomly assigned to two separate groups in the first group of atorvastatin tablets produced by Sobhan Pharmaceutical Company will be prescribed once in the morning, the dose will be determined based on the risk of cardiovascular complications in each individual, after 4 weeks the level of blood lipids will be measured again.
Category
Treatment - Drugs

2

Description
Control group: in the second group of atorvastatin tablets produced by Sobhan Pharmaceutical Company will be prescribed once in the evening, the dose will be determined based on the risk of cardiovascular complications in each individual, after 4 weeks the level of blood lipids will be measured again.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Neda Meftah
Street address
Ayatollah Rouhani Hospital., Ganjafrooz St., University Square., Babol Town., Mazandaran Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Sepide Tavanaeifard
Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Position

Resident

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available