# 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)

**Phone**
+98 11 3223 8301

**Email address**
s.tavanaeifard@mubabol.ac.ir

**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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nedameftah@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Babol University of Medical Sciences
**Full name of responsible person**
Reza Ghadimi
**Street address**
Ayatollah Rouhani Hospital., Ganjafrooz St., University Square., Babol Town., Mazandaran Province
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rezaghadimi@yahoo.com
**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

**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

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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