

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of Atorvastatin Gel on improvement of diabetic foot ulcer : A Prospective, double-Blind, Randomized,clinical Trial

#### Protocol summary

##### Study aim

Preparation of atorvastatin gel formulation and evaluation of its therapeutic effects on the diabetic foot ulcer

##### Design

A randomized ,double-blind clinical trial with parallel control and intervention groups. Patients will be treated with atorvastatin gel and placebo. The generation of random numbers is done with Random allocation software, and 60 samples will be assigned in 15 blocks of 4.

##### Settings and conduct

Topical diabetic wound treatment in patients referring to Imam Khomeini hospital in Sari: researcher, participant, clinical caregiver and outcome assessor are blinded in this trial. Diabetic patients with grade 1 and 2 diabetic foot ulcers (based on Wagner's rating) were randomly selected and divided into intervention and control groups. Then, they use the formulations once every three days for a month.

##### Participants/Inclusion and exclusion criteria

Patients with grade 1 and 2 diabetic wounds (based on Wagner's rating) who are over 18 years old, will be included in the study. Patients with the following conditions will be excluded: having diseases that causing wound healing problems (Like liver and kidney failure, heart failure, various cancers, vasculitis), taking alcohol and cigarettes or any drugs ,the presence of infectious ulcers requiring amputations.

##### Intervention groups

Control group: Patients in this group will use a placebo gel. Gel formulation without any drugs (formulation without active ingredient, and contains propylene glycol, ethanol, glycerin and carbomer obtained from Dr. Mojallali Industrial Chemical Complex Co.) ,once every 3 days, for one month will be used. Intervention group: Patients in this group will use an atorvastatin 2% gel .Gel formulation containing the drug (active ingredient: atorvastatin 2% powder, Tehran Chemie Pharmaceutical

CO) ,once every 3 days, for one month will be used.

##### Main outcome variables

Permanent pain, changes in the degree of ulcer, wound scope

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100107003014N24**

Registration date: **2021-06-18, 1400/03/28**

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

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

##### Registration date

2021-06-18, 1400/03/28

##### Registrant information

##### Name

Shahram Ala

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-11, 1398/08/20

##### Expected recruitment end date

2022-03-10, 1400/12/19

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Atorvastatin Gel on improvement of diabetic foot ulcer : A Prospective, double-Blind, Randomized,clinical Trial

**Public title**  
Evaluation the effects of Atorvastatin on diabetic foot

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Having Diabetic Wounds Grade 1 and 2 Based on Wagner Ratings Having a single sore in the legs or the ends of the fingers (and the sole of the leg or heel) Which has lasted at least 4 weeks  
**Exclusion criteria:**  
Having diseases that causing wound healing problems Like liver and kidney failure, heart failure, various cancers, vasculitis Taking alcohol and cigarettes or any drugs The presence of infectious ulcers requiring amputations.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be treated with atorvastatin gel and placebo using the blocking method. The generation of random numbers is done with Random allocation software, and 60 samples will be assigned in 15 blocks of 4. All products used in the study are completely identical in terms of appearance and packaging, and their content will be characterized by a four-digit code.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The gel containing the active ingredient and placebo gel is in the same package with the same color and appearance. The gel tubes were coded by the first performer (data analyzer).Therefore, patients, clinical colleagues, and working students do not know any of the codes' meanings. The tubes are randomly selected and used by patients.

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Ethics department of Mazandaran University of Medical Sciences, Mazandaran University of Medical Sciences, Vice chancellor for research, Moallem square, sari, Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

33971- 48157

#### Approval date

2020-01-01, 1398/10/11

#### Ethics committee reference number

IR.MAZUMS.REC.1398.1260

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic foot ulcer

#### ICD-10 code

E11.621

#### ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

## Primary outcomes

### 1

#### Description

Changing the degree of ulcer

#### Timepoint

Wound grade measurement at the beginning of the study (before intervention) And 7, 14 and 21 days After starting to use a drug gel

#### Method of measurement

Measuring the size of the wound, the amount of erythema, the amount of pain (VAS criteria) and Irritation

### 2

#### Description

Permanent pain

### Timepoint

Measuring the amount of pain at the beginning of the study, the first week, the second, third ,and fourth weeks after the start of the study, is evaluated and recorded.

### Method of measurement

Visual Analogue Scale

### 3

#### Description

Wound Scope

#### Timepoint

Measuring the wound scope at the beginning of the study, the first week, the second, third ,and fourth weeks after the start of the study, is evaluated and recorded.

#### Method of measurement

Observation with measuring instruments

## Secondary outcomes

### 1

#### Description

Side effect during treatment

#### Timepoint

The type of side effect measured during treatment at the first, second, third and fourth week after the start of treatment.

#### Method of measurement

observation and according to questionnaire

## Intervention groups

### 1

#### Description

Control group: Patients in this group (selected randomly and double blindly) will use a placebo gel. Gel formulation without any drugs (formulation without active ingredient, and contains propylene glycol, ethanol, glycerin and carbomer obtained from Dr. Mojallali Industrial Chemical Complex Co.) ,once every 3 days, for one month

#### Category

Placebo

### 2

#### Description

Intervention group: Patients in this group (selected randomly and double blindly) will use an atorvastatin 2% gel .Gel formulation containing the drug(active ingredient: atorvastatin 2% powder obtained from Tehran Chemie Pharmaceutical CO .In addition to the active ingredient, the formulation contains propylene glycol, ethanol, glycerin and carbomer) ,once every 3 days, for one month

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital of Sari

##### Full name of responsible person

Dr Shahram Ala

##### Street address

Imam Khomeini Hospital, Amir-Mazandarani street, Sari, Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

333131-48166

##### Phone

+98 31 3336 1700

##### Email

ems115@mazums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research and technology, Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Majid Saeedi

##### Street address

Payambar azam university complex, Mazandaran University of Medical Sciences, Faculty of pharmacy, Km 18 Khazar abad road, Sari, Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3325 7230

##### Email

msaeedi@mazums.ac.ir

##### Web page address

<http://pajooheshi.mazums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice chancellor for research and technology, Mazandaran 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

**Postal code**

4815733971

**Phone**

+98 11 1354 3083

**Fax****Email**

sh204ala@yahoo.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Parham Salehi

**Position**

Pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of pharmacy, Payambar Azam university complex, Mazandaran University of Medical Sciences, Km 18 Khazar abad road, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 1354 3083

**Fax****Email**

parhamsalehi053@gmail.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Shahram Ala

**Position**

Clinical pharmacy specialist, Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of pharmacy, Payambar Azam university complex, Mazandaran University of Medical Sciences, Km 18 Khazar abad road, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

+98 11 1354 3083

**Fax****Email**

sh204ala@yahoo.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Shahram Ala

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of pharmacy, Payambar Azam university complex, Mazandaran University of Medical Sciences, Km 18 Khazar abad road, Sari

**City**

Sari

**Province**

Mazandaran

**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**

Not applicable

**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