Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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 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
Postal code
4815733971
Phone
+98 11 1354 3083
Fax
Email
sh204ala@yahoo.com

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

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