

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of efficacy of topical formulation of atorvastatin 1% in grade and depth of diabetic foot ulcer

Protocol summary

Summary

This study was designed to evaluate the efficacy of topical Atorvastatin 1% in a double blind randomized placebo controlled trial on grade 1, stage A diabetic foot ulcer (according to University of Texas Foot Wound Classification System). Hundred patients with grade 1, stage A diabetic foot ulcer were assigned into two groups (50 each) to receive topical formulation of atorvastatin 1% or placebo for 21 days. The grade and depth of ulcer will be evaluated after 7, 14 and 21 days. The results will be compared in these two groups to assess the possible effect of topical atorvastatin 1% on diabetic foot ulcer healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208123449N9**

Registration date: **2012-09-07, 1391/06/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-09-07, 1391/06/17

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

Email address

khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-11-19, 1391/08/29

Expected recruitment end date

2014-02-22, 1392/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of topical formulation of atorvastatin 1% in grade and depth of diabetic foot ulcer

Public title

Evaluation of efficacy of topical formulation of atorvastatin 1% in diabetic foot ulcer healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients with Grade 1 and stage A diabetic foot ulcers Exclusion criteria: Patients' age less than 18 or greater than 80 years old; Diabetic foot ulcer greater than grade 1 and stage A; Patients with infected ulcers; Sensitivity to topical formulation, Patients who need surgical intervention for their wounds

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Ghods Ave
City
Tehran
Postal code
Approval date
2012-08-02, 1391/05/12
Ethics committee reference number
91-02-33-17758

Health conditions studied

1
Description of health condition studied
Diabetic food ulcers
ICD-10 code
L97
ICD-10 code description
Ulcer of lower limb, not elsewhere classified

Primary outcomes

1
Description
grade of diabetic foot ulcer
Timepoint
before intervention and then 7, 14 and 21 days after
after intervention
Method of measurement
ulcers will be evaluated according to University of Texas
Foot Wound Classification System

Secondary outcomes

1
Description
depth (stage) of diabetic ulcers
Timepoint
before intervention and then 7, 14 and 21 days after
after intervention
Method of measurement
ulcers will be evaluated according to University of Texas
Foot Wound Classification System

Intervention groups

1
Description
Patients in intervention (Drug) group will be receive
standard treatment of diabetic foot (including topical or
systemic antibiotic) in addition to topical formulation of
atorvastatin 1% once daily for 3 weeks.
Category
Treatment - Drugs

2
Description
Patients in control (placebo) group will be receive
standard treatment of diabetic foot in addition to placebo
(Base of ointment formulation without drug) once daily
for 3 weeks.
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Imam Khomeini
Full name of responsible person
Hossein khalili
Street address
Keshavarz BLV,
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran university of Medical Sciences
Full name of responsible person
Fatemeh Saeedi
Street address
Ghods avenu, Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number

91-02-33-17758

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

Yes

Title of funding source

Tehran university of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hosein Khalili

Position

associated professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty