Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6695 4715

Fax

+98 66954715

Email

khalilih@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Pharm D

Other areas of specialty/work

Street address

Faculty of Pharmacy, Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6695 4715

Fax

+98 66954715

Email

khalilih@tums.ac.ir

Web page address

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