

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Efficacy of topical formulation of Atorvastatin 1% in bed sore healing

Protocol summary

Tehran University of Medical Sciences

Summary

This study was designed to evaluate the efficacy of topical Atorvastatin 1% in a double blind randomized placebo controlled trial on pressure sore healing. Hundred patients with grade 1 or 2 bed sore were assigned into two groups (50 each) to receive topical formulation of atorvastatin 1% or placebo for 14 days. The grade of bed sore will be evaluated after 7 and 14 days. The results will be compared in these two groups to assess the possible effect of topical atorvastatin 1% on bed sore healing.

Expected recruitment start date

2011-02-20, 1389/12/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of topical formulation of Atorvastatin 1% in bed sore healing

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102273449N4**

Registration date: **2011-03-31, 1390/01/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-03-31, 1390/01/11

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

Public title

Efficacy of topical formulation of Atorvastatin 1% in bed sore healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Grade 1 or 2 bed sore diagnosed by the pharmacist according to The 2-digit Stirling scale

Exclusion criteria: pregnancy or lactation, hypersensitivity reaction to topical formulation, elevated ALT and/or AST to more than 3 times the upper limit of normal with clinical manifestations of liver failure or more than 5 times the upper limit of normal without clinical manifestations of liver failure, unwillingness for entering in the study or discontinuation of follow up

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Pharmaceutical Science Research Center

Street address

Pharmaceutical Sciences Research Center, Faculty of Pharmacy, Tehran University of Medical Sciences, Poursina Avenue

City

Tehran

Postal code

Approval date

2011-01-23, 1389/11/03

Ethics committee reference number

1389/3/3

Health conditions studied

1

Description of health condition studied

Grade 1 or 2 bed sore

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer (Pressure ulcer)

Primary outcomes

1

Description

Grade of bed sore

Timepoint

7 and 14 days after topical formulation

Method of measurement

evaluation of bed sore grade according to The 2-digit Stirling scale by pharmacist

Secondary outcomes

empty

Intervention groups

1

Description

Control: topical placebo formulation (base of formulation without active ingredient of atorvastatin) once daily for 14 days

Category

Placebo

2

Description

Intervention: topical Atorvastatin 1% once daily for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Abollahi

Street address

Tehran university of Medical Sciences, Enghelab Ave, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Research Center, 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

Hossein Khalili

Position

Associate Professor

Other areas of specialty/work

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Email

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Web page address

Person responsible for updating data

Contact

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