Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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.

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

Tehran University of Medical Sciences

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

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
evaluationof 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 Khomenin 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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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