Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Efficacy of topical formulation of Sildenafil10% in bed sore healing

Protocol summary

Summary

This study was designed to evaluate the efficacy of topical Sildenafil 10% 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 sildenafil 10% 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 sildenafil 10% on bed sore healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105303449N6**
Registration date: **2011-06-03, 1390/03/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-06-03, 1390/03/13

Registrant information

Name
Hossein Khalili
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-07-01, 1390/04/10

Expected recruitment end date

2012-07-01, 1391/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of topical formulation of Sildenafil10% in bed sore healing

Public title

Efficacy of topical formulation of Sildenafil10% 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

To **139 years** old

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 sildenafil) once daily for 14 days
Category
Treatment - Drugs

2

Description
Intervention: topical sildenafil 10% once daily for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان امام خمینی
Full name of responsible person
Street address
City
تهران

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