Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy of topical formulation of sildenafil 10% in grade and depth of diabetic foot ulcer

Protocol summary

Summary

This study was designed to evaluate the efficacy of topical sildenafil10% 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 sildenafil10% 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 sildenafil10% on diabetic foot ulcer healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208123449N10**
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

2013-01-18, 1391/10/29

Expected recruitment end date

2016-02-22, 1394/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of topical formulation of sildenafil 10% in grade and depth of diabetic foot ulcer

Public title

Evaluation of efficacy of topical formulation of sildenafil 10% in diabetic foot ulcer healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetic patients with Grade 1, stage A diabetic foot ulcers according to University of Texas Foot Wound Classification System, wh0 received standard care Exclusion criteria: patients with grade and stage more than 1, sensitivity reaction to topical formulation, unwillingness for entering in the study or discontinuation of follow up

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: **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
Tehran University of Medical Sciences
Street address
Ghods Ave, Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2012-08-15, 1391/05/25
Ethics committee reference number
91-02-33-17752

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 case (intervention) group will be receive usual treatment of diabetic foot (including topical or systemic antibiotics) in addition to topical sildenafil ointment 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 Hospital
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
Mrs Fatemeh Saeidi
Street address
Ghods Ave
City
Tehran
Grant name
Grant code / Reference number

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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Person responsible for updating data

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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