Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparing efficacy of nifedipine ointment and placebo on healing of bedsore in critically ill patients: A clinical trial

Protocol summary

Summary

The goal of this study is comparing efficacy of nifedipine ointment and placebo on healing of bedsore. In a double blind, randomized clinical trial, 100 critically ill patients with grade 1 or 2 of bedsore will be simply randomized in two equal groups; topical nifedipine 3% or placebo ointment. Patients with history of nifedipine hypersensitivity, severe bedsore requiring antibiotic therapy, hospitalization less than 14 days in ICU and worsening of bedsore during treatment course will be excluded from the study. Recruited patients will be received nifedipine or placebo ointment twice daily topically for 14 days. Nifedipine and placebo ointments are same in packaging and the responsible researchers and patients are blinded. Grade of bedsore will be evaluated at baseline and after 14 days of interventions based on the 2-digit Stirling Scale. Change in grade of sore is outcome of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705073449N23**
Registration date: **2017-06-04, 1396/03/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-04, 1396/03/14

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

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khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-04-25, 1396/02/05

Expected recruitment end date

2018-04-25, 1397/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of nifedipine ointment and placebo on healing of bedsore in critically ill patients: A clinical trial

Public title

Nifedipine ointment in treatment of bedsore

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Critically ill adult patients; with grade 1 or 2 of bedsore; hospitalized in Intensive Care Unit (ICU) for at-least 14 days; without history of nifedipine hypersensitivity reaction. Exclusion Criteria: Patients with severe bedsore requiring antibiotic therapy; worsening of bedsore during treatment course.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase
2-3
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
Method of randomization: Simple randomization method using the random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Ghods Ave.
City
Tehran
Postal code
Approval date
2017-04-24, 1396/02/04
Ethics committee reference number
IR.TUMS.PSRC.REC.1396.2132

Health conditions studied

1

Description of health condition studied
Bedsore
ICD-10 code
L89.0
ICD-10 code description
The ulcer appears as a defined area of persistent redness (erythema) in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues, without skin loss

Primary outcomes

1

Description
Grade of bedsore
Timepoint
At ICU admission and then day 14 of hospitalization
Method of measurement
2-digit Stirling scale

Secondary outcomes

empty

Intervention groups

1

Description
Nifedipine 3% ointment (formulated in the faculty of pharmacy affiliated to Tehran University of Medical Sciences) twice daily topically cover all sores area for 14 days
Category
Treatment - Drugs

2

Description
Placebo ointment (formulated in the faculty of pharmacy affiliated to Tehran University of Medical Sciences) twice daily topically cover all sores area for 14 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hossein Khalili
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
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
Vice Chancellor for Research, 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
Name of organization / entity
Tehran University of Medical Sciences
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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