Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing efficacy of pentoxifyllin ointment and placebo in treatment of bedsore in patients hospitalized in intensive care unit

Protocol summary

Summary

The goal of this study is comparing efficacy of pentoxifyllin ointment and placebo in treatment of bedsore. In a double blinded randomized clinical trial, 100 critically ill patients with grade 1 or 2 of bedsore will be simply randomized in two equal groups; topical pentoxifyllin 5% or placebo ointment. Patients with history of pentoxifyllin hypersensitivity, severe bedsore requiring antibiotic therapy, less than 14 days in ICU hospitalization and worsening of bedsore during treatment course will be excluded from the study. Recruited patients will be received pentoxifyllin or placebo ointment twice daily topically for 14 days. Pentoxifyllin and placebo ointments are same in packaging and the responsible researchers and patients will be blinded. Grade of bedsore will be evaluated at baseline and after 14 days of interventions based on the 2-digit Stirling scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402233449N16**
Registration date: **2014-03-13, 1392/12/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-13, 1392/12/22

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

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2014-02-01, 1392/11/12

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of pentoxifyllin ointment and placebo in treatment of bedsore in patients hospitalized in intensive care unit

Public title

Pentoxifyllin ointment in treatment of bedsore

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Critically ill patients with grade 1 or 2 of bedsore, who will be hospitalized in Intensive Care Unit (ICU) for at-least 14 days and without history of pentoxifyllin hypersensitivity. Exclusion Criteria: Patients with severe bedsore requiring antibiotic therapy and worsening of bedsore during treatment course will be excluded from the study.

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: based on 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
2014-02-01, 1392/11/12
Ethics committee reference number
92-03-33-24364

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
Pentoxifyllin 5% 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Pharm. D

Other areas of specialty/work

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 6695 4715

Fax

Email

khalilih@tums.ac.ir

Web page address

Person responsible for updating data

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