

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparing efficacy of nifedipine ointment and placebo on healing of bed sore 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 bed sore. In a double blind, randomized clinical trial, 100 critically ill patients with grade 1 or 2 of bed sore will be simply randomized in two equal groups; topical nifedipine 3% or placebo ointment. Patients with history of nifedipine hypersensitivity, severe bed sore requiring antibiotic therapy, hospitalization less than 14 days in ICU and worsening of bed sore 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 bed sore 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

###### 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

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 bed sore in critically ill patients: A clinical trial

###### Public title

Nifedipine ointment in treatment of bed sore

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

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

**Full name of responsible person**

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**Position**

Pharm. D

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Web page address****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*