

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The assesment of the effect of topical simvastatin 2% ointment in patients with bed sore grade 1,2: A randomized controlled clinical trial

#### Protocol summary

##### Study aim

Determining the effectiveness of Simvastatin 2% topical ointment in the treatment of grade 1 and 2 bed sores

##### Design

Phase one and two randomized clinical trial on 104 patients with bedsores Grade 1 and 2, will be used for the randomization of Othello.

##### Settings and conduct

In this clinical study, phase one and two, the effectiveness of simvastatin 2% ointment on bed sores, 104 patients with grade 1 and 2 bed sores hospitalized in Rasoul Akram Hospital were randomly divided into two groups through a table of numbers. One group will be treated with 2% simvastatin ointment and one group will be treated with a new dressing for 14 days. Patients will be evaluated for wound healing on days 7 and 14.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with grade 1 and 2 bed sores based on physician diagnosis and Stirling Pressure Sore Severity Scale Criteria for not entering: 1. Patients who have grade 3 and 4 bed sores or their sores are progressing to grade 3 and 4. 2. Patients whose wound is acutely infected or at high risk of infection. 3. Patients whose length of hospital stay is less than 14 days. 4. Pregnant and lactating women

##### Intervention groups

The intervention group will be treated with simvastatin 2% ointment prepared in the laboratory of Islamic Azad School of Pharmacy for 14 days. The control group will be treated with the new dressing for 14 days.

##### Main outcome variables

Reduce wound size and grade

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210423051047N1**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

##### Registration date

2021-05-16, 1400/02/26

##### Registrant information

###### Name

somayyeh nasiripour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 86701

###### Email address

nasiripours@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-06, 1400/03/16

##### Expected recruitment end date

2021-08-11, 1400/05/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The assesment of the effect of topical simvastatin 2% ointment in patients with bed sore grade 1,2: A randomized controlled clinical trial

##### Public title

The effect of simvastatin 2% ointment on bed sores

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with grade 1 and 2 bed sores

### Exclusion criteria:

Patients with severely infected wounds or a high risk of infection. Patients whose length of hospital stay is less than 14 days. Pregnant and lactating women

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **104**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization using a table of random numbers  
People will be given a two-digit code, and to select sample people from the table, it will randomly start from a point in the table in the direction of the column.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad Tehran Medical Sciences University- Pharmacy and Pharmaceutical Bra

##### Street address

First Glacier St.Gholhak. Dr. Shariati St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1941933111

#### Approval date

2020-11-10, 1399/08/20

#### Ethics committee reference number

IR.IAU.PS.REC.1399.214

## Health conditions studied

### 1

#### Description of health condition studied

Stage I Bedsore

#### ICD-10 code

L89.0

#### ICD-10 code description

Stage I decubitus ulcer and pressure area

### 2

#### Description of health condition studied

Stage II Bedsore

#### ICD-10 code

L89.1

#### ICD-10 code description

Stage II decubitus ulcer

## Primary outcomes

### 1

#### Description

Reducing wound size

#### Timepoint

7 and 14 days after the intervention

#### Method of measurement

Ruler

## Secondary outcomes

### 1

#### Description

Reduce the length of hospital stay

#### Timepoint

Daily after intervention

#### Method of measurement

Observational

## Intervention groups

### 1

#### Description

The intervention group consisted of 52 patients with grade 1 and 2 bed sores who were treated with simvastatin 2% ointment (as daily) prepared in the laboratory of the Islamic Azad School of Pharmacy for 14 days.

#### Category

Treatment - Drugs

### 2

#### Description

The control group consisted of 52 patients with grade 1 and 2 bed sores who will be treated with a new dressing (as daily) for 14 days.

#### Category

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Somayyeh Nasiripour

**Street address**

Niayesh St. Sattarkhan

**City**

Tehran

**Province**

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**Postal code**

1445613131

**Phone**

+98 21 6655 8811

**Email**

nasiripours@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farshad Hashemian

**Street address**

Yakhchal St.Gholhak. Dr. Shariati St

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

1

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**
**Type of organization providing the funding**

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Somayyeh Nasiripour

**Position**

Assistant Professor of Clinical Pharmacy

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The results of the study will be published as an article.

**When the data will become available and for how long**

September 2021

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

After the written letter requesting the information to be published, the request will be evaluated by the responsible persons and the information will be available while protecting the rights of the responsible persons.

**From where data/document is obtainable**

Dr. Somayyeh Nasiripour, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences Email: nasiripours@yahoo.com

**What processes are involved for a request to access data/document**

After the written letter requesting the information to be published, the request will be evaluated by the responsible persons and the information will be available while protecting the rights of the responsible persons.

**Comments**