

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of the Effectiveness of topical cream 3% Simvastatin on the percentage of wound healing of grade 2 and 3 Bedsore in Diabetic and non\_diabetic people compared to Placebo and Standard treatment

#### Protocol summary

##### Study aim

Evaluation of the clinical effect of topical cream of Simvastatin on bedsore healing ratio

##### Design

A randomized controlled clinical trial with single, double blind, phase 2 on 20 patients

##### Settings and conduct

The study site is Taleghani Hospital in Ahwaz, wound clinic. Dimensions of patient's Bessores are measured by clinical caregiver using the Wound healing ratio formula. The caregiver and the patient are blind and therapeutic creams based on codes on creams and the codes inside the envelope is given to the patients.

##### Participants/Inclusion and exclusion criteria

Entry conditions: informed consent, Diabetes and bedsore, No entry conditions: allergy to Statins and pregnant or lactating

##### Intervention groups

In the intervention group the therapeutic effect of topical simvastatin is investigated. The control group has no active ingredient to compare the efficacy.

##### Main outcome variables

Reduce the size of the patient's wound

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200602047634N1**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **prospective**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

##### Registration date

2020-06-05, 1399/03/16

#### Registrant information

##### Name

Afarin Aghajari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5235 5757

##### Email address

afarinaghajari01@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2020-06-13, 1399/03/24

#### Expected recruitment end date

2020-07-14, 1399/04/24

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the Effectiveness of topical cream 3% Simvastatin on the percentage of wound healing of grade 2 and 3 Bedsore in Diabetic and non\_diabetic people compared to Placebo and Standard treatment

#### Public title

Effect of topical Simvastatin in treatment of Bedsore

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients who sign informed consent Patients with Diabetes Patients with grade 2 or 3 Bessores

**Exclusion criteria:**

Patients with a history of allergy to Statins Patients who are pregnant or lactating

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of block randomization is that people are divided into four blocks and each block after entering the treatment room, the random permutations are written in a sealed envelope like Placebo Placebo Medicine Medicine, Medicine Placebo Medicine Placebo and..., take the Drug and give it to the clinical caregiver and the clinical caregiver without knowing the coding in the envelope gives the Sick. The Placebo code is A and the Medicine code is B.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Initially, the code for the Placebo is considered by the researcher to be Placebo A and Medicine B. In sealed envelopes, the Researcher writes the code as random permutations and gives clinical caregiver so that patients can pick up an envelope of their choice then the clinical caregiver based on the random permutation and the code on the cream tube gives patients Placebo or Medicine.

**Placebo**

Used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Golestan st, Ahvaz University of Medical Sciences

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Approval date**

2019-05-18, 1398/02/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.178

**Health conditions studied****1****Description of health condition studied**

Bed sore

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

30% reduction in wound size

**Timepoint**

Measure the size of the wound at the beginning of the study and 7, 14 and 21 days after starting topical Simvastatin

**Method of measurement**

Ruler of wound

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Topical cream containing 3% Simvastatin, apply on clean wound Twice daily, a 50 gram cream every week, treatment for 3 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: Topical cream without Simvastatin, with Water- absorbing base, in order to compare with the treatment group, apply on clean wound Twice daily, a 50 gram cream every week, treatment for 3 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Taleghani hospital  
**Full name of responsible person**  
Afarin Aghajari  
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Mostaan St, Amaniye  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
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Dr. Mohammad Badavi  
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Ahvaz Jondishapour University of Medical Sciences,  
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itc@ajums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz University of Medical Sciences  
**Proportion provided by this source**  
100  
**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**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences

**Full name of responsible person**  
Afarin Aghajari  
**Position**  
Pharmacy student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for scientific inquiries

#### Contact

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Reza Ganji  
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Assistant professor  
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## Person responsible for updating data

#### Contact

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not 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