Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Bedsores 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
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Afarin Aghajari
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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 Bedsores

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 comqmittee of Ahvaz University of Medical Sciences

Street address
Golestan st, Ahvaz University of Medical Sciences

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Khouzestan

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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
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Sponsors / Funding sources

1

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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
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
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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