

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Produce and evaluation of the topical effect of simvastatin cream 3% on improving wound healing in diabetic patients compared with placebo: In a randomized, triple -blind, placebo-controlled clinical trial phase 2

Protocol summary

2020-05-30, 1399/03/10

Study aim

Evaluation of the topical effect of Simvastatin on improving wound healing in diabetic patients

Design

A randomized, triple -blind, placebo-controlled clinical trial with factorial groups

Settings and conduct

The formulation of drug and placebo packaged in tubes with quite the same color and appearance. Patients, physician and analyzer will not know the group of them. The drug group receives a cream containing Simvastatin. The placebo group receives a cream without Simvastatin. Both groups receive standard oral and topical treatment.

Participants/Inclusion and exclusion criteria

Diabetic patients with foot ulcer in grade 2 or 3 and age over 18 years

Intervention groups

The drug group receives a cream containing Simvastatin. The placebo group receives a cream without Simvastatin. Both groups receive standard oral and topical treatment.

Main outcome variables

Wound area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191010045051N1**

Registration date: **2020-05-30, 1399/03/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-30, 1399/03/10**

Update count: **0**

Registration date

Registrant information

Name

Mozhde Ghomashbafzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3622 5820

Email address

mozhde.ghomashbaf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-07-06, 1399/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Produce and evaluation of the topical effect of simvastatin cream 3% on improving wound healing in diabetic patients compared with placebo: In a randomized, triple -blind, placebo-controlled clinical trial phase 2

Public title

Evaluation of the topical effect of simvastatin on improving wound healing in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients with foot ulcer in grade 2 or 3

Exclusion criteria:

Diabetic patients with foot ulcers with a wound surface greater than 10 cm Patients in need of amputation

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method. Six-person blocks were designed including three patients receiving placebo and three patients receiving the drug. The form in the envelope was delivered to the Infectious Disease Physician. Patients, physician and analyzer will not know the group of formulation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The formulation of drug and placebo packaged in tubes with quite the same color and appearance. Patients, physician and analyzer will not know the group of formulation.

Placebo

Used

Assignment

Parallel

Other design features

The intervention group receives the cream containing simvastatin and the control group receives base cream (without simvastatin). Both groups receive standard treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz jondishapour University of Medical Sciences

Street address

Shahid Sherafat Ave., Farhang Blvd., ShushtarTown

City

Shushtar

Province

Khouzestan

Postal code

6451944543

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.AJUMS.REC.1398.141

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E10.5

ICD-10 code description

Type 1 diabetes mellitus with circulatory complications

Primary outcomes

1

Description

Wound area

Timepoint

Measurement of wound area at baseline and 14 and 28 days after topical cream application

Method of measurement

Ruler

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

14 and 28 days after topical cream application

Method of measurement

Number of hospital stay days

Intervention groups

1

Description

Intervention group: Patients in this group twice daily for 4 weeks use 3% Simvastatin cream topically on diabetic foot ulcer. The product formulation is in the form of a cream with a absorbent base and Simvastatin powder has been purchased from Loghman Company.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group twice daily for 4 weeks use the base cream(without simvastatin) topically on diabetic foot ulcer.The base cream has a completely similar formulation to the intervention group and only lacks Simvastatin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Mozhde Ghomashbafzade

Street address

Shahid Sherafat Ave., Farhang Blvd., ShushtarTown

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Email

mozhde.ghomashbaf@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Badavi

Street address

Esfand st

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Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3221 8617

Email

info@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

Mozhde Ghomashbafzade

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mozhde Ghomashbafzade

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available