

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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

**City**

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**Province**

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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

**City**

Ahvaz

**Province**

Khuzestan

**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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Ahvaz University of Medical Sciences

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## Person responsible for updating data

### Contact

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Ahvaz University of Medical Sciences

**Full name of responsible person**

Mozhde Ghomashbafzade

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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