

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluating the effect of topical simvastatin 2% ointment on the healing of diabetic foot ulcer in comparison with the routine treatment

#### Protocol summary

##### Study aim

Evaluating the effectiveness of topical simvastatin 2% ointment on the healing of diabetic foot ulcer Comparing the effectiveness of simvastatin 2% ointment with the routine treatment The rate of side effects caused by simvastatin 2% ointment

##### Design

A phase 1, randomized and single blinded clinical trial with control group on 60 patients with grade 2 diabetic foot ulcer

##### Settings and conduct

Group 1: Patients with grade 2 diabetic foot ulcer and admitted to Rasoul Akram Hospital for 14 days will be treated with simvastatin 2% ointment twice a day. Group 2: In the control group, patients use simple foam dressing.

##### Participants/Inclusion and exclusion criteria

The age of the patient should not be less than 18 years and not more than 70 years. A patient with Wagner grade 2 diabetic foot ulcer Not using topical antibiotics and other topical treatment for the patient A patient with no symptoms of septicemia, septic shock or organ dysfunction syndrome

##### Intervention groups

Patients are divided into two groups of 30 patients, treatment and control. Simvastatin 2% ointment will be used in the treatment group, and simple foam dressing will be used in the control group. In both treatment and control groups, the treatment will continue twice a day for two weeks. All wounds are covered with Vaseline gauze.

##### Main outcome variables

1. Grading the type and severity of the wound
2. Evaluating the apparent progress of wound healing
3. Evaluation of drug side effects
4. Blood factors related to infection and inflammation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200325046854N3**

Registration date: **2023-10-28, 1402/08/06**

Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**

Update count: **0**

##### Registration date

2023-10-28, 1402/08/06

##### Registrant information

##### Name

Maryam Farasatinasab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4460 4800

##### Email address

maryfarasati@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-16, 1402/08/25

##### Expected recruitment end date

2024-02-14, 1402/11/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of topical simvastatin 2% ointment on the healing of diabetic foot ulcer in comparison with the routine treatment

**Public title**

topical simvastatin in diabetic foot ulcer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

A patient with Wagner grade 2 diabetic foot ulcer Not using topical antibiotics for the patient A patient with no symptoms of septicemia, septic shock or organ dysfunction syndrome The age of the patient should not be less than 18 years and not more than 70 years.

**Exclusion criteria:**

Receive other topical treatments for diabetic foot ulcers

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Among the patients referred to the clinic or hospitalized in Rasoul Akram Hospital, numbering is done in odd and even numbers. Odd patients will be in the treatment group and even patients will be in the control group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participant does not know the type of treatment.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Research Ethics Committees of Islamic Azad Tehran Medical Sciences University - Pharmacy and Pharmac

**Street address**

shariati St, Gholhak

**City**

Tehran

**Province**

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**Postal code**

1941933111

**Approval date**

2023-01-02, 1401/10/12

**Ethics committee reference number**

IR.IAU.PS.REC.1401.439

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

diabetic foot ulcer

**ICD-10 code**

E08.621

**ICD-10 code description**

Diabetes mellitus due to underlying condition with foot ulcer

**Primary outcomes****1****Description**

Grading the type and severity of the wound

**Timepoint**

Day 0, 7 and 14

**Method of measurement**

The size, amount of discharge and smell of the wound

**2****Description**

Evaluating the apparent progress of wound healing

**Timepoint**

Day 0, 7 and 14

**Method of measurement**

Imaging

**Secondary outcomes****1****Description**

Possible side effects

**Timepoint**

Day 0, 7 and 14

**Method of measurement**

Descriptive

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

Intervention group:Patients in Rasoul Akram Hospital, diagnosed with Wagner grade 2 diabetic foot ulcer, will be treated with simvastatin 2% ointment. Ointment will be administered twice a day for 2 weeks and the wound will be covered with Vaseline gauze.

**Category**

Treatment - Drugs

**2****Description**

Control group: Patients in Rasoul Akram Hospital, diagnosed with Wagner grade 2 diabetic foot ulcer, will be treated with Simple foam dressing for 2 weeks and twice a day.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Zeynab Yasin

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Niyayesh St, Sattar Khan

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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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**

Iran 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**

Islamic Azad University

**Full name of responsible person**

Fatemeh Jamali

**Position**

Pharmacy student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Maryam Farasatinasab

**Position**

Assistant Professor of Clinical Pharmacy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Azadeh Eshraghi

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Assistant Professor of Clinical Pharmacy

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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

Yes - There is 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

As an article

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

8 months after the end of the study

### To whom data/document is available

Researchers and specialist in academic and scientific institutions

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

In case of a written request to the study authorities and while preserving the copyright, patient data will be made available to applicants.

### From where data/document is obtainable

Maryam Farasatinasab, Assistant Professor of Clinical Pharmacy, Iran University of Medical Sciences. Email: maryfarasati@gmail.com

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

At the formal request to the person in charge of study

### Comments