

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the N-Acetyl cysteine effect on therapeutic outcome of diabetic foot ulcers

Protocol summary

Study aim

Assessment of the N-Acetyl cysteine effect on therapeutic outcome of diabetic foot ulcers

Design

An open-label, randomized clinical trial study with parallel groups and phases 3 on 50 patients. Randomization will be done according to block randomization method using Random allocation software.

Settings and conduct

This open-label, randomized clinical trial study will be conducted on 50 patients of grades 3 and 4 of diabetic foot ulcers in Urmia Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

In this study, 50 patients over 18 years with grades 3 and 4 of diabetic foot ulcers based on Wegener criteria will be included. The main exclusion criteria include allergy to N-acetyl cysteine and sulfur products, Other causes of ulcers except diabetes include trauma and etc., taking drugs such as: corticosteroids at a minimum dose equivalent to 40 mg of prednisolone, mycophenolate, cyclosporine, tacrolimus, rituximab, and hospitalized patients for a diabetic foot ulcer in the last one month and receiving injection antibiotic treatment.

Intervention groups

Patients in the intervention group will receive 600 mg N-acetyl cysteine orally every 12 hours for 14 days in addition to routine treatments. In the control group, routine diabetic foot ulcer treatments will be performed.

Main outcome variables

Wound size, number of wounds and healing time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220928056051N2**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **prospective**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

Laya Hooshmand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 7286

Email address

hooshmand.l@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the N-Acetyl cysteine effect on therapeutic outcome of diabetic foot ulcers

Public title

Assessment of the N-Acetyl cysteine effect on diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years Grade 3 or 4 diabetic foot ulcer according to Wagner criteria

Exclusion criteria:
Allergy to N-Acetyl cysteine and sulfur products
Pregnancy and breastfeeding Other causes of ulcers except diabetes include trauma and others A generated- ulcers skin disease Impossibility of taking tablets orally
Patients treated with chemotherapy or radiotherapy drugs Taking drugs such as: corticosteroids at a minimum dose equivalent to 40 milligrams of prednisolone, mycophenolate, cyclosporine, tacrolimus, rituximab Hospitalized for a diabetic foot ulcer in the last month and receiving injection antibiotic treatment
Stenosis and severe cramping of the lower limbs vessels based on vascular sonography Chronic alcohol consumption of more than 250 cc daily

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be implemented. Patients will be allocated to intervention or control groups based on generated numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق بیمارستان امام خمینی، دانشگاه علوم پزشکی ارومیه

Street address

Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran..

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.047

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

Z86.31

ICD-10 code description

Personal history of diabetic foot ulcer

Primary outcomes

1

Description

wound size

Timepoint

Before and 14 days after the intervention

Method of measurement

Wound area in cm2 based on imaging

2

Description

Wound Number

Timepoint

Before and 14 days after the intervention

Method of measurement

Clinical examination

3

Description

healing time

Timepoint

After intervention

Method of measurement

Days

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

After intervention

Method of measurement

Days

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive 600 mg N-acetyl cysteine orally every 12 hours for 14 days in addition to routine treatments.

Category

Treatment - Drugs

2

Description

Control group: In the control group, routine diabetic foot ulcer treatments will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Laya Hooshmand

Street address

Imam Khomeini hospital., Ershad Ave., Modarress Blvd., Urmia., Iran

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Phone

+98 44 3345 7286

Email

hooshmand.l@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

Street address

Urmia University of Medical Sciences., Resalat street., Jihad Blvd., Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Laya Hooshmand

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

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Province

West Azarbaijan

Postal code

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Phone

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Email

hooshmand.l@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Laya Hooshmand

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Blvd., Urmia., Iran

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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

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Laya Hooshmand

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address