

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of ANSIL(Silver nanoparticles) solution on Diabetic foot wounds: A double-blind clinical trial

Protocol summary

Study aim

Determination of the effect of ANSIL solution (silver nanoparticle) on the severity of diabetic foot ulcers

Design

A clinical trial with a control group with parallel groups, double-blind, randomized, phase 3 on the sample size with 80 patients that randomized with GraphPad software.

Settings and conduct

This is a double-blind, placebo-randomized study using ANSIL solution or placebo in people with diabetic foot ulcers. Subjects are randomly assigned to intervention and control groups. Patients referred to Imam Reza Hospital of Tabriz University of Medical Sciences with signs and symptoms related to diabetic ulcers are included in the study through include/exclusion criteria and with informed written consent.

Participants/Inclusion and exclusion criteria

Patients with diabetes who take insulin and have diabetic foot ulcers and are in the age range of 18 to 80 years. Patients with infectious wounds, sensitivity to topical formulation Patients who need surgery for their wounds are excluded from the study.

Intervention groups

Group 1: 20 patients with diabetic foot ulcers receive 50ppm doses of ANSIL solution twice a day for 28 days.
Group 2: 20 patients with diabetic foot ulcers receive 100ppm dose of ANSIL solution twice a day for 28days
Group 3: 20 patients with diabetic foot ulcers receive 150ppm doses of ANSILsolution twice a day for 28days.
Control group: Treatment of diabetic foot ulcers in 20 patients in a way other than the mentioned method for28days.

Main outcome variables

The severity of a diabetic foot ulcer is measured using the Texas Scoring System.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190701044062N9**

Registration date: **2021-10-11, 1400/07/19**

Registration timing: **prospective**

Last update: **2021-10-11, 1400/07/19**

Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name

manouchehr khoshbaten

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 3010

Email address

mkhoshbaten@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-16, 1400/07/24

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ANSIL(Silver nanoparticles) solution on Diabetic foot wounds: A double-blind clinical trial

Public title

Effect of ANCIL on diabetic foot wounds

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic patients taking insulin with diabetic wound Age range 18 to 80 years

Exclusion criteria:

Patients with infectious wounds Sensitivity to topical formulations Patients who need surgery for their wounds

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using simple randomization using GraphPad software and by a secretary who does not interfere with other stages of the investigation. People will be randomly divided into groups A, B, C, D.

Blinding (investigator's opinion)

Double blinded

Blinding description

A solution that has an active ingredient in ANCIL with a solution that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the solution themselves do not differ in terms of odor and color, and are completely indistinguishable. (This action was taken by the manufacturer company of the solution). The important point is that the patient is told that the solution used for the patient may be medication or medication. Clinicians or outcome assessors and blind patients will be blinded

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medic

Street address

Central Office of Tabriz University of Medical Sciences
Tabriz -Golghast St.- Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.TBZMED.REC.1399.1169

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

Diabetic foot ulcers

ICD-10 code

Z86.31

ICD-10 code description

Personal history of diabetic foot ulcer

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

The severity of a diabetic foot ulcer is measured using the Texas Scoring System.

Timepoint

Before the intervention and 7, 14, 21, and 28 days after the intervention

Method of measurement

The severity of diabetic foot ulcers in patients receiving ANCIL and placebo solution before the intervention and on days 7, 14, 21, and 28 after the intervention is measured using the Texas scoring system. Texas scoring system for diabetic foot ulcers to 4 degrees (0 to 3 Grade 1 is classified according to wound depth, infection, and ischemia as Grade 0 before or after the wound has healed, Grade 1 of a superficial wound that has not involved a tendon, capsule, or bone. Grade 2: The wound has penetrated a tendon or capsule. Grade 3: The wound has penetrated the bone or joint. Stage A: clean wound, Stage B: non-infectious and non-ischemic, Stage C: ischemic and non-ischemic, Stage D: Infectious and ischemic wound.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients with diabetic foot ulcer receive 50ppm of ANCIL solution twice a day for 28 days and bandaged on the wound. ANCIL solution: ASEPE company introduces ANSIL for the treatment and repair of damaged tissues caused by diabetic wounds, bedsores, and injuries caused by severe burns. Various substances are used in the solution, including plant extracts of silymarin, zinc oxide, silver, ascorbic acid, glycerin, alpha tocopherol, retinoids, and phylloquinone. The type of material and their composition determine that it has the greatest effect on wound healing and strengthening.

Category

Treatment - Drugs

2

Description

Intervention group: 20 patients with diabetic foot ulcer receive 100ppm of ANCIL solution twice a day for 28 days and bandaged on the wound. ANCIL solution: ASEPE company introduces ANSIL for the treatment and repair of damaged tissues caused by diabetic wounds, bedsores, and injuries caused by severe burns. Various substances are used in the solution, including plant extracts of silymarin, zinc oxide, silver, ascorbic acid, glycerin, alpha tocopherol, retinoids, and phylloquinone. The type of material and their composition determine that it has the greatest effect on wound healing and strengthening.

Category

Treatment - Drugs

3

Description

Intervention group: 20 patients with diabetic foot ulcer receive 150ppm of ANCIL solution twice a day for 30 days and bandaged on the wound. ANCIL solution: ASEPE company introduces ANSIL for the treatment and repair of damaged tissues caused by diabetic wounds, bedsores, and injuries caused by severe burns. Various substances are used in the solution, including plant extracts of silymarin, zinc oxide, silver, ascorbic acid, glycerin, alpha tocopherol, retinoids, and phylloquinone. The type of material and their composition determine that it has the greatest effect on wound healing and strengthening.

Category

Treatment - Drugs

4

Description

Control group: Treatment of diabetic foot ulcers in 20 patients in a way other than the mentioned method for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz

Full name of responsible person

Manouchehr Khoshbaten

Street address

Golgasht St, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 1334 3010

Email

mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

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Tabriz

Province

East Azarbaijan

Postal code

5166/15731

Phone

+98 41 3335 9680

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Shima Khademi

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No1026,East Second floor, Azarabadegan Ave, Third daneshgah Ave, Nasr Town

City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Manouchehr Khoshbaten

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Adult digestive and liver

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Shima Khademi

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No1026,East Second floor, Azarabadegan Ave, Third daneshgah Ave, Nasr Town

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Postal code

5158375751

Phone

0416628155

Email

Khademishima94@gmail.com

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

Yes - There is a plan to make this available

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

Title and more details about the data/document

A portion of the data will be shared.

When the data will become available and for how long

2023-2024

To whom data/document is available

Researchers and academic staffs

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

Request via email: Khademishima94@gmail.com Shima Khademi

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

Request via email: Khademishima94@gmail.com Shima Khademi

Comments