# 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 ANCIL 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 ANCIL solution twice a day for 28 days.
Group 2: 20 patients with diabetic foot ulcers receive 100ppm dose of ANCIL solution twice a day for 28days
Group 3: 20 patients with diabetic foot ulcers receive 150ppm doses of ANCILsolution 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 receive50ppm of ANCIL solution twice a day for 28days 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 receive100ppm of ANCIL solution twice a day for 28days 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 receive150ppm 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 28days

**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

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Tabriz

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## 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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**Email**
reasearch-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

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
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**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

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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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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**