Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluating the effectiveness of nano silver spray on digital ulcers of patients with scleroderma

Protocol summary

Study aim
Evaluating the effectiveness of nano silver spray on digital ulcers of patients with scleroderma

Design
A placebo-controlled, randomized, double-blinded, phase 2-3 clinical trial on 50 patients. Block randomization was used for randomization.

Settings and conduct
The study will be conducted as a double-blind clinical trial in experimental and control groups. Fifty patients with finger ulcers, caused by scleroderma, who referred to rheumatology clinic of Imam Reza hospital, and met the study inclusion and exclusion criteria, will be included in the study. Then, they will be randomly assigned to experimental or control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients aged > 18 years 2. Patients with finger ulcers, caused by scleroderma, with mild to moderate severity (1-10 new ulcers in the fingers involving surface epithelial cells, the epidermis, the dermis, or the subcutaneous tissue) and without purulent discharge 3. Patients who signed our patient consent permission form. Exclusion criteria: 1. Patients with severe finger ulcers (more than 10 new ulcers in the fingers, extensive tissue destruction with damage to muscle, supporting structures (eg, tendon, joint capsule) and bone, necrosis and gangrene) Patients who do not use the spray regularly

Intervention groups
In the intervention group, patients use silver nanospray 4 times a day (every 6 hours) on the finger ulcers. In the control group, patients use placebo spray 4 times a day (every 6 hours) on the finger ulcers.

Main outcome variables
The size of ulcers, (DUS) digital ulcer score, the healing time of ulcers

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191221045837N5**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**
Update count: **0**

Registration date
2023-09-09, 1402/06/18

Registrant information
Name
Zinat Heidari
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-22, 1402/10/01
Expected recruitment end date
2025-12-22, 1404/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluating the effectiveness of nano silver spray on digital ulcers of patients with scleroderma

Public title
Evaluating the effectiveness of silver spray in scleroderma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Patients aged > 18 years 2. Patients with finger ulcers, caused by scleroderma, with mild to moderate severity (1-10 new ulcers in the fingers involving surface epithelial cells, the epidermis, the dermis, or the subcutaneous tissue) and without purulent discharge 3. Patients who signed our patient consent permission form.
Exclusion criteria:
1. Patients with severe finger ulcers (more than 10 new ulcers in the fingers, extensive tissue destruction with damage to muscle, supporting structures (eg, tendon, joint capsule) and bone, necrosis and gangrene) Patients who do not use the spray regularly
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization Randomization tool: https://www.sealedenvelope.com/ How to make a random sequence: To perform this method, the number of intervention groups (two groups A and B), the volume of each block (4 in each block) and sample size (50 patients) were entered into the website. Then, the site creates a randomization list of 13 blocks, each contains 4 patients
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double blinded in which the subjects, evaluators, analysts, sample allocators will be unaware of the intervention and control groups. Drugs and placebo, numbered 1-50, will be identified and distinguished by the drug manufacturing company, which belong to the drug or placebo group based on a random list prepared from www.sealedenvelope.com. The physician, patients, and analyst will remain unaware of the type of formulation until the work is completed. Patients receive one of the medicine containers, number 1-50, respectively. The list will be decrypted when completed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central department of Mashhad University of Medical Sciences, next to Alton Tower, Daneshgah Street, Mashhad, Khorasan Razavi Province, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Approval date
2023-08-19, 1402/05/28
Ethics committee reference number
IR.MUMS.REC.1402.138

Health conditions studied

1

Description of health condition studied
scleroderma
ICD-10 code
M34
ICD-10 code description
Systemic sclerosis [scleroderma]

Primary outcomes

1

Description
The size of ulcers
Timepoint
weekly
Method of measurement
Length x Width: Measure the greatest length (head to toe) and the greatest width (side to side) using a centimeter ruler.

2

Description

(DUS) digital ulcer score

Timepoint

weekly

Method of measurement

Length x depth of ulcer

3

Description

The healing time of ulcers

Timepoint

weekly

Method of measurement

Observing the appearance of the ulcer

Secondary outcomes

1

Description

Intensity of pain in patients with ulcers

Timepoint

weekly

Method of measurement

visual analogue scale (VAS)

2

Description

The quality of life of patients

Timepoint

weekly

Method of measurement

Health-Related Quality of Life (HRQOL) questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, patients use silver nanospray 4 times a day (every 6 hours) on the finger ulcers.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients use placebo spray 4 times a day (every 6 hours) on the finger ulcers.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Zinat Heidari

Street address

Imam Reza hospital, Imam Reza Square, Ibn-e Sina Avenue, Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person
Zinat Heidari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
At the end of study, all medical records of patients will be shared.
When the data will become available and for how long
The access period starts 6 months after the publication.
To whom data/document is available
Researchers affiliated to academic, scientific and industrial institutes
Under which criteria data/document could be used
No one is allowed to use the documents except the principal researcher.
From where data/document is obtainable
Send an email to Dr. Zinat Heidari. heidarizn@mums.ac.ir
What processes are involved for a request to access data/document
Send an email to Dr. Zinat Heidari. heidarizn@mums.ac.ir
Comments