

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)

Phone

+98 51 3180 1584

Email address

heidarizn@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

Heidarizn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Moohebaty

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

91357345

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

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

Street address

Faculty of Pharmacy, University Campus, Azadi Square, Mashhad, Khorasan Razavi.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1584

Email

heidarizn@mums.ac.ir

Person responsible for scientific 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

Street address

Faculty of Pharmacy, University Campus, Azadi Square, Mashhad, Khorasan Razavi.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1584

Email

heidarizn@mums.ac.ir

Person responsible for updating data**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

Street address

Faculty of Pharmacy, University Campus, Azadi Square, Mashhad, Khorasan Razavi.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1584

Email

heidarizn@mums.ac.ir

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