

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

A comparative study of the therapeutic effect of collagen superabsorbent powder containing silver nanoparticles 15 ppm and 1% silver sulfadiazine ointment on the healing of bedsore.

Protocol summary

Study aim

Determining the therapeutic effect of superabsorbent collagen powder containing 15ppm silver nano particles compared to 1% silver sulfadiazine ointment on bed wound healing.

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, phase 3 on 68 patients

Settings and conduct

Wound healing clinics and nursing homes in Isfahan city
Measuring the surface of the wound using caliper software. Washing the wound with 0.9% sterile saline. A few puffs of Nivasha nano silver spray are applied on the surface of the wounds to sterilize the surface of the wounds. After that, 1% silver sulfadiazine or superabsorbent collagen powder containing silver nanoparticles is poured on the wounds, and a layer of vaseline gauze and sterile gauze are placed on the wounds, respectively. It is placed and bandaged by bandage. The wound dressing is changed every 48 hours in the case of the intervention group and daily in the case of the comparison group until the wound is completely healed.

Participants/Inclusion and exclusion criteria

Patients aged 35-80 years with at least 30-day-old ulcers. The wound should be defined as a cavitory bed wound, Wagner grade 3-4. No local or systemic signs of infection, With normal CRP and leukocyte levels

Intervention groups

34 patients in the intervention group will be dressed with collagen superabsorbent powder containing silver nanoparticles (with a concentration of 15 ppm) and 34 patients in the comparison group will be dressed with 1% silver sulfadiazine ointment (trade name Flamexin).

Main outcome variables

Frequency distribution of recovery rate , Average recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230621058552N2**

Registration date: **2023-07-13, 1402/04/22**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **0**

Registration date

2023-07-13, 1402/04/22

Registrant information

Name

maryam aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 2206

Email address

maryam.ghaei2008@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2025-02-03, 1403/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the therapeutic effect of collagen superabsorbent powder containing silver nanoparticles 15 ppm and 1% silver sulfadiazine ointment on the healing of bedsore.

Public title

Comparing collagen superabsorbent powder containing silver nanoparticles 15 ppm and 1% silver sulfadiazine ointment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 35-80 years with at least 30-day-old ulcers. The wound should be defined as a cavitory bed wound, Wagner grade 3-4. No local or systemic signs of infection, with normal CRP and leukocyte levels

Exclusion criteria:

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

They are divided into two intervention and comparison groups through the table of random numbers. These tables have random numbers in both row and column directions, which usually reach 99 rows and columns, and the numbers of the rows and columns are in blocks of five digits next to each other and in a separated form to facilitate its use. Then we find out the exact number of people in the community and give them a code or machine gun number respectively. To select sample people from the table, we randomly start from a point of the table (by closing the eyes and placing a finger or the tip of the pen on the table) in the direction of the row or column. The chosen small number is actually the code of an individual from the community that is chosen as a sample. This work continues until a small number can be selected for the number of sample people. After the sample volume is complete, the sampling work ends.

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar jarib Street. Azadai Square, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8173963181

Approval date

2023-03-14, 1401/12/23

Ethics committee reference number

IR.ARI.MUI.REC.1401.338

Health conditions studied

1

Description of health condition studied

Bed Sore

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Frequency distribution of improvement rate in patients treated with collagen superabsorbent powder and silver sulfadiazine ointment

Timepoint

Measurement of the wound surface at the beginning of the study (before the start of the intervention) and every 48 hours after starting the use of collagen superabsorbent powder and silver sulfadiazine ointment.

Method of measurement

Using caliper software with a unit of mm

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After washing the wound with 0.9% sterile saline, the wound is placed in the open air for 5 minutes so that its surface is completely dry, then a few puffs of Nivasha nano silver spray (with a concentration of 15 ppm and health code 9655068437941620, manufactured by Nano Alvand Arad Company) is applied on the surface of the wounds to sterilize the surface of

the wounds. After that, collagen superabsorbent powder containing silver nanoparticles (with a concentration of 15 ppm, manufactured by Nano Alvand Arad company) is poured on the wounds and a layer of Vaseline and sterile gauze is placed on the wounds and bandaged. The wound dressing is changed every 48 hours until the wound heals completely.

Category

Treatment - Drugs

2**Description**

Control group: After washing the wound with 0.9% sterile saline, the wound is placed in the open air for 5 minutes so that its surface is completely dry, then a few puffs of Nivasha nano silver spray (with a concentration of 15 ppm and health code 9655068437941620, manufactured by Nano Alvand Arad Company) is applied on the surface of the wounds to sterilize the surface of the wounds. After that, 1% silver sulfadiazine ointment (with the trade name Flamexin, manufactured by Emad Darman Pars Pharmaceutical Company) is used, and a layer of Vaseline and sterile gauze is placed on the wounds and bandaged. Wound dressings are changed daily until the wound heals completely.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Wound healing clinics and nursing homes in Isfahan city

Full name of responsible person

Dr. Morteza Sanaguizade Isfahani

Street address

The first treatment clinic.Jey Street.Isfahan..

City

Isfahan

Province

Isfahan

Postal code

8173963183

Phone

+98 31 3230 0286

Email

drsanagoo52@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

Street address

Building No. 4, Research and Technology Vice-Chancellor, Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

askari@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Aghaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

Street address

Sedigheh Tahereh hospital . Khoram Street. Jomhori Square.

City

Isfahan

Province

Isfahan

Postal code

81876-98191

Phone

+98 31 3339 0100

Email

maryam.ghaei2008@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Zabihollah Shahmoradi

Position

Director of the Skin and Skin Diseases Research Center

Latest degree

Specialist

Other areas of specialty/work

Others

Street address

Leishmaniasis And Skin Diseases Research Center, Sedighe And Tahereh Clinic, Khoram Street, Jomhoori Square.

City

Isfahan

Province

Isfahan

Postal code

81876-98191

Phone

+98 31 3339 0100

Email

emrc@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Aghaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

Street address

Sedighe And Tahereh Clinic, Khoram Street, Jomhoori Square ,

City

Isfahan

Province

Isfahan

Postal code

81876- 98191

Phone

+98 31 3339 0100

Email

maryam.aghaei2008@gmail.com

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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available