Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 cavitary 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)

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+98 31 3626 2206

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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 cavitary 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
Isfehan

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

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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

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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

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

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Position
Director of the Skin and Skin Diseases Research Center

Latest degree
Specialist

Other areas of specialty/work
Others

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Latest degree
Ph.D.

Other areas of specialty/work
Medical Biology

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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