

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of alginate gel containing silver nanoparticles in the healing of skin wounds - Phase 1 and 2 clinical trial

Protocol summary

Study aim

Evaluation of the effect of alginate gel containing silver nanoparticles in the healing of skin wounds

Design

Randomized and single-blind clinical trial in two intervention and control groups on 30 patients

Settings and conduct

30 patients with grade 2 wounds were selected from the medical centers of Kerman University of Medical Sciences, after giving oral explanations and obtaining written consent. Then the patients are divided into 2 control and intervention groups. In the intervention group, after washing the wound with normal saline, silver gel is placed on the site. The dressing is changed every 48 hours. On days 0, 3, 7, and 10, microbial culture is performed to check the reduction of infection. (Every time the dressing is changed, a photograph is taken of the wound site in order to check the healing process of the wound). Silversulfadiazine ointment is used instead of silver alginate gel in the control group, and it will be done in the same way as the intervention group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 95 years, patients confirmed to have grade 2 ulcers, without antibiotic treatment, exclusion criteria: patients who do not want to continue the clinical trial for any reason. Patients with underlying diseases such as uncontrolled diabetes, autoimmune diseases, or patients undergoing chemotherapy drugs, etc., or wounds that become infected.

Intervention groups

Intervention group: In this group, after washing the wound with normal saline, patients put silver gel on the site and put a protective dressing on it. Control group: In this group, after washing the wound with normal saline, common wound treatment that includes silver sulfadiazine and nitrofurazone ointment is applied to the wound every other day.

Main outcome variables

Measurement of wound surface, amount of wound bacteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057844N1**

Registration date: **2023-04-12, 1402/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-12, 1402/01/23**

Update count: **0**

Registration date

2023-04-12, 1402/01/23

Registrant information

Name

Mohammad Javad Mirzaei-Parsa

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3121 5682

Email address

mj.mirzaei@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-09-10, 1402/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of alginate gel containing silver nanoparticles in the healing of skin wounds - Phase 1 and 2 clinical trial

Public title

The effect silver nanoparticles in the healing of skin wounds

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Conditions for entering the study: age between 18 and 95 years old, having grade 2 wounds, no history of antibiotic use, conditions for leaving the study: patients who do not want to continue the clinical trial for any reason. Patients with underlying diseases such as uncontrolled diabetes, autoimmune diseases, or patients undergoing chemotherapy drugs, etc. Wound infection. In these cases, the patient will be removed from the research units and the treatment method will be changed according to the doctor's opinion.

Exclusion criteria:**Age**

From **18 years** old to **95 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients to the intervention and control groups is done by the block diagnosis method and using blocks of 4, in each of the blocks 2 people are placed in the intervention group and 2 people in the control group, but they must be regularly to be placed It will be a random form that this will be done with Winpappy software

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher numbers the formulation of the container containing the medicinal formula so that the patient is unaware of the contents of the container.

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.KMU.REC.1401.018

Health conditions studied**1****Description of health condition studied**

wound healing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Degree of wound, presence or absence of infection

Timepoint

Days zero, 3, 7 and 10

Method of measurement

Examining the size of the wound and using a ruler and ImageJ software, examining microbial cultures

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this group, after washing the wound with normal saline, patients put silver gel on the site and put a protective dressing on it.

Category

Treatment - Drugs

2

Description

Control group: In this group, after washing the wound with normal saline, common wound treatment that includes silver sulfadiazine and nitrofurazone ointment is applied to the wound every other day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Mahsa Nazemzadeh

Street address

Shefa Medical Education Center, Kausar Blvd, Kerman

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Recruitment center

Name of recruitment center

Shahid Bahonar hospital

Full name of responsible person

Mahsa Nazemzadeh

Street address

Shahid Bahonar Hospital, Qorani St, Kerman

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Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Abazar pournajaf

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Ayatollah Rouhani Hospital, Ganj Afroz St, University Square, Babol, Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Javad Mirzaei-Parsa

Street address

Innovation Center for Stem Cells and Regenerative Medicine, Shafa street, Kerman

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Email

mj.mirzaei@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohamad Javad Mirzaei-Parsa

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Nanotechnology

Street address

Stem Cell Innovation Center and Regenerative
Medicine, Shefa Crossroads, Kerman

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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mohamad Javad Mirzaei-Parsa

Position

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Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Mohamad Javad Mirzaei-Parsa

Position

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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

No - There is not 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

Title and more details about the data/document

Non-identifiable personal data of the participants, study protocol, statistical analysis map, informed consent form will be shared after the end of the study.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data can be analyzed and exploited within the framework of the study protocol, but the right to publish the data will be with the research team. People who wish to have access to data or documents should send their written request to the project manager's email and explain their reason for needing these data and documents and how they will use them.

From where data/document is obtainable

Corresponding of project

What processes are involved for a request to access data/document

The applicant must first submit a request including the requested data or document, the reason for the need for this data or document and the uses he will make of it along with a brief introduction of himself and the company or university where he works. This request will be reviewed as soon as possible, and then, taking into account the conditions of the request, if the answer is positive, the data will be provided to the applicant.

Comments