

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Active adhesive hydrogel as second grade wound dressing

Protocol summary

Study aim

Determining the effect of active adhesive hydrogel consisting of polyacrylamide, hydroxyethyl cellulose, and polyquaternium 7 in second degree wound healing

Design

A clinical trial of drugs with two control and intervention groups, randomized with online software, phase 3 on 30 patients

Settings and conduct

The intervention groups are treated for 14 days with dressing changes every other day. After receiving explanations at Dr. Soltani's clinic and training on how to use them, photos of the wound healing process are taken every other day. Then, the surface of the wounds is analyzed by ImageJ software.

Participants/Inclusion and exclusion criteria

The conditions for entering/exiting the study are as follows: Inclusion criteria: male and female patients with second-degree skin ulcers are included in the study. Exclusion criteria: patients with diabetes, HIV, diseases and problems of the immune system, pregnant women, lactating women or those who intend to become pregnant, uncontrolled infection and people with various skin sensitivities.

Intervention groups

The control group received a conventional silver-impregnated dressing The intervention group receiving active hydrogel dressing

Main outcome variables

Acceleration of skin wound healing compared to the control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240130060864N1**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Farjam Goudarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 919 521 6837

Email address

farjam.goudarzi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-18, 1403/01/30

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Active adhesive hydrogel as second grade wound dressing

Public title

Adhesive hydrogel for wound dressing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients include men and women with second-degree skin ulcers

Exclusion criteria:

Diabetes HIV Diseases and problems of the immune system Pregnancy Lactating or those planning to become pregnant Uncontrolled infection All types of skin allergies

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used using blocks of 4. A third person who is not involved in the process of diagnosing and evaluating patients will create a random sequence using the site: <https://www.sealedenvelope.com> and the number of blocks will be determined based on the sample size. Each patient will be given a unique code that can be created on this site. Therefore, concealment is observed and the people involved in the study do not know in which group the next person will be placed and they will not know about the random sequence; Only the statistics consultant will know about the random sequence and the codes will remain with them.

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 Kermanshah Medical Sciences

Street address

Beheshti BLVD

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Kermanshah

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Kermanshah

Postal code

6714869914

Approval date

2024-01-16, 1402/10/26

Ethics committee reference number

IR.KUMS.REC.1402.503

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

Second degree skin wound

ICD-10 code

T14.1

ICD-10 code description

Open wound of unspecified body region

Primary outcomes**1****Description**

The rate of skin wound closure compared to the control group

Timepoint

14 days

Method of measurement

Photographing the wound and analyzing it semi-quantitatively with ImageJ software

Secondary outcomes**1****Description**

skin itching

Timepoint

During the intervention

Method of measurement

Oral

2**Description**

Erythema

Timepoint

During the intervention

Method of measurement

Oral

3**Description**

Dry skin feeling

Timepoint

During the intervention

Method of measurement

Oral

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

Control group: In this group, common commercial dressings that are dry and impregnated with silver are used. These dressings only play the role of preventing infection by silver and isolating the wound environment

from the surrounding atmosphere.

Category

Treatment - Devices

2

Description

Intervention group: In this group, the unique hydrogel of this study is used for volunteers. This dressing is placed on the wound so that it covers the wound. Then they are changed every other day for 14 days.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Keyvan Soltani's specialized clinic

Full name of responsible person

Dr. Keyvan Soltani

Street address

Saadi Street Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

Street address

Building No. 2 Medical Sciences - Research and Technology Vice-Chancellor, Shahid Beheshti Blvd. , Kermanshah

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farjam Goudarzi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Faculty of Medicine, Razi Blvd., Kermanshah, Kermanshah

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farjam Goudarzi

Position

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Other areas of specialty/work

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Person responsible for updating data

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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

Due to the confidentiality of people's information and the possibility of commercialization of the dressing, it is not possible to share data

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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable