

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the therapeutic effect of dressing containing Silver(Ag coat) in the process of healing skin blisters caused by limb fractures

Protocol summary

Study aim

Evaluation of the therapeutic effect of dressing containing Ag coat in the process of healing skin blisters caused by limb fractures

Design

The therapeutic research plan was to use two types of dressings containing silver and gaz vaseline and to compare the size of the wound surface , the rate of recovery, pain, visit time and cost,over time. 40 patients referred to Kashani Hospital in Isfahan. They were randomly selected and randomly assigned to silver dressing and vaseline gaz dressing groups using secret random cards.

Settings and conduct

This study was conducted on patients with skin blisters caused by bone fractures in Kashani Hospital, Isfahan. Blister areas were photographed on days 0, 7, and 14 and compared by mosaic software. Also, the amount of pain was compared by the Vas questionnaire, the time of visit and number of dressing, and cost of dressing between the two groups. Participants were blinded to grouping.

Participants/Inclusion and exclusion criteria

all patients with blister due to bone fracture, aged between 18-65 and Consent to participate in the study.

Intervention groups

Among the 40 selected patients, 31 patients were divided into two groups of 15 people with silver dressing (case) and 16 people with Vaseline gas (control) according to the entry and exit criteria. The wound surface of the patients was photographed by a photographer based on protocol and analyzed by Mosaic software.

Main outcome variables

wound area, duration of visit, Number of dressings,Net cost of dressing, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221207056744N1**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

Sahar Lalehzar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3235 6684

Email address

saharsadatlalehzar4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-03, 1401/10/13

Expected recruitment end date

2023-08-12, 1402/05/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of dressing containing Silver(Ag coat) in the process of healing skin blisters caused by limb fractures

Public title

Therapeutic effect of dressing containing silver on skin blister

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all patients with blister due to bone fracture aged between 18-65 years old Consent to participate in the study

Exclusion criteria:

Sensitivity to silver Amputation indication patients who did not agree to participate in the study those who did not participate in the study until the end and did not come for follow-up sessions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a pioneering randomized trial that compares the effectiveness of two dressings containing silver(Ag coat) and gaz vaseline among patients with skin blisters caused by bone fractures who were randomly selected from patients referred to the Kashani Medical Training Center. After the selection, the participants were randomly assigned to the experimental and control groups using lottery cards, so that the results of their allocation to the groups were accessible only after the completion of the initial evaluations by the research staff.

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 science

Street address

Hazar Jarib St., Isfahan University of Medical Sciences and Health Services, central headquarters

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-04-16, 1401/01/27

Ethics committee reference number

IR.MUI.MED.REC.1401.025

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

blister due to bone fracture

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

wound area

Timepoint

Measurement of wound area at the beginning of the study (before the intervention), day 7 and day 14

Method of measurement

Taking a photo of the wound at a distance of 15 cm and perpendicular to the wound and analyzing it using the mosaic software.

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

pain

Timepoint

Measurements on day 0, 7 and 14

Method of measurement

VAS score questioner

2**Description**

Duration of visit

Timepoint

Measurements on day 0, 7 and 14

Method of measurement

The length of time that the wound specialist visits the patient to change the dressing

3

Description

Number of dressings

Timepoint

From day 0 to day 14

Method of measurement

Counting the number of dressings by a wound expert

4

Description

Net cost of dressing

Timepoint

From day 0 to day 14

Method of measurement

The price of the total number of dressings used in the entire 14 days of the study

Intervention groups

1

Description

Intervention group: Intervention group: silver dressing (Ag coat) was placed on the blister for 14 days and changed every one week. On days 0, 7, and 14, blisters were photographed. Wound area was calculated by mosaic software and size changes were measured over time.

Category

Treatment - Drugs

2

Description

Control group: Vaseline gaz dressing was placed on the blister for 14 days and changed every day. On days 0, 7, and 14, blisters were photographed. Wound area was calculated by mosaic software and size changes were measured over time.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Isfahan Kashani Hospital

Full name of responsible person

Mehdi Teimouri

Street address

Isfahan - Kashani St. - Kashani Hospital

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saharsadatlahzar4@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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

No

Title of funding source

Isfahan university of medical science

Proportion provided by this source

1

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

Mehdi Teimouri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Sahar sadat Lalehzar
Position
general practitioner
Latest degree
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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)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available to everyone

Under which criteria data/document could be used

There will be no special condition

From where data/document is obtainable

Sahar sadat Lalehzar saharsadatlalehzar4@gmail.com

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

There will be no special process, we will respond only by sending an email

Comments