

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the Effectiveness of Aloe Vera Gel and Conventional Dressing on Wound Healing and pain of Second Grade Bed sore .

Protocol summary

Study aim

evaluation effects of Aloe vera gel versus conventional dressing on the healing rate and pain of second degree pressure ulcer

Design

In this study, the units were selected from the study population by convenience sampling or available sampling method and then randomly divided into two experimental groups. The two groups were matched in terms of wound size, wound depth, absence of underlying disease and wound location. The first group or the experimental group was treated with aloe vera gel. In this way, after washing the wound daily with normal saline, a layer of aloe vera gel with a diameter of 5 mm was placed on the wound and covered with two or three layers of sterile gauze and bandaged on the wound with a sterile bandage. The second group or the control group was treated with normal saline, so that this group was covered with two or three layers of sterile gas daily after washing the wound with normal saline and bandaged on the wound with a sterile bandage.

Settings and conduct

This clinical trial will be carried out at Imam Khomeini Hospital of Shahkhamin Hospital and Valiasr Hospital in Arak,

Participants/Inclusion and exclusion criteria

Participants had grade 2 pressure ulcers. The patient's wound was not contaminated. Not all subjects had symptomatic infections in different parts of the body before entering the study. They were willing to participate in the research and were able to answer the questions. If patients withdrew from treatment after admission to the study or if any allergies and drug sensitivities to the treatment occurred, patients were excluded from the study.

Intervention groups

all patients with stage 2 pressure ulcer who sign the inform consent

Main outcome variables

|Healing rate, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180715040478N2**

Registration date: **2021-08-17, 1400/05/26**

Registration timing: **retrospective**

Last update: **2021-08-17, 1400/05/26**

Update count: **0**

Registration date

2021-08-17, 1400/05/26

Registrant information

Name

Azam Malekhoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

Azam.malekhoseini@khomeinums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-08, 1398/10/18

Expected recruitment end date

2021-02-08, 1399/11/20

Actual recruitment start date

2020-01-08, 1398/10/18

Actual recruitment end date

2021-02-08, 1399/11/20

Trial completion date

2021-02-08, 1399/11/20

Scientific title

Comparison of the Effectiveness of Aloe Vera Gel and Conventional Dressing on Wound Healing and pain of Second Grade Bed sore .

Public title

The Effect of Aloe Vera Gel in Bed sore .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants have grade 2 pressure ulcer The patient's wound should not be contaminated with contaminants Before entering the study did not use any substance other than drinking water on the wound Participants should not have symptomatic infections of different parts of the body before entering the study Willingness to participate in research Be able to answer questions

Exclusion criteria:

Unwillingness of patients or their families to participate in the study.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **56**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were selected from the study population by Simple randomization or available sampling method (coin tossing) were placed in each group of ten people, after which the background characteristics of patients in each group were evaluated. The next patient to enter the study was admitted to a group that minimized the overall difference between the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomized double- blind (Patients and assessor)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Khomein University of Medical Sciences

Street address

Azadi Street

City

Khomein

Province

Markazi

Postal code

38818-58573

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.KHOMEIN.REC.1398.007

Health conditions studied

1

Description of health condition studied

bed sore

ICD-10 code

L89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes

1

Description

size of wound

Timepoint

The first, seventh and fourteenth day

Method of measurement

Using tape measure

2

Description

The amount of pain

Timepoint

The first, seventh and fourteenth day

Method of measurement

Visual Analogue Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Normal saline group

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Hospital of Arak

Full name of responsible person

Azam malekhoseini

Street address

Arak, Imam Khomeini St., Vali Asr Square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Azam malekhoseini

Street address

Arak, Ayatollah Ghaffari St., intersection of Vali Asr St.

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3817834467

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malekhoseni.aram@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Azam malekhoseini

Position

Coach

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Arak: Sardasht - Basij Square - Academic Complex of the Great Prophet (PBUH) - Facilities

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Person responsible for scientific inquiries

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

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

Data Dictionary

Not applicable