Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

Treatment - Drugs

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.
City
Arak
Province
Markazi
Postal code
3817834467
Phone
+98 86 3226 7892
Email
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
Academic

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
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Email
malekhoseni.aram@gmail.com

Person responsible for scientific 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
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Email
malekhoseni.aram@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Azam malekhosini
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
City
Arak
Province
Markazi
Postal code
38481-7-6341
Phone
+98 86 3417 3520
Email
malekhoseni.aram@gmail.com

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