

# 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.

**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**

## 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**

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**Postal code**

38481-7-6341

**Phone**

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**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**

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## Person responsible for updating data

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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