

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of Aloe Vera gel on prevention of pressure sore among patients hospitalized in orthopedic ward

#### Protocol summary

##### Summary

This study intends to study Aloe Vera gel in the prevention of pressure ulcers in patients hospitalized in the orthopedic ward. This research is a random triple-blind clinical trial that patients, researchers and analysts aren't informed of the intervention and control groups. After obtaining informed consent, 80 patients admitted in the orthopedic ward because of fracture and immobility and having the specifications of taking part in the research are selected based on purposive sampling. They are divided in two groups by Random Allocation. Both groups will be examined after patient reception using Braden tool and those who score less than 14 (they are at risk of moderate to severe bed sores) are enrolled. In both groups, the daily care will be done by nurses to prevent bed ulcers for patients. The researcher moisturizes the same areas in the test group as moisturized in the control group by an applicator. Furthermore, in the intervention group after checking the absence of an allergic reaction, pure Aloe Vera gel is applied twice a day (at 9a.m and 9 p.m) on the areas of hip, sacrum and heel. In the control group the researcher moisturizes the same areas by placebo (gel, water and starch) using an applicator and removes the material from the skin by a tissue. Sacrum, hip and heel are controlled on days 3, 7 and 10 in terms of presence or absence of symptoms of pressure ulcers based on the scale of pressure ulcers and scale of Braden risk of pressure ulcer

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016051027825N1**

Registration date: **2016-09-07, 1395/06/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-07, 1395/06/17

##### Registrant information

###### Name

Fatemeh Mehrabi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3457 5029

###### Email address

f.mehrabi@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2016-06-25, 1395/04/05

##### Expected recruitment end date

2016-09-26, 1395/07/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Aloe Vera gel on prevention of pressure sore among patients hospitalized in orthopedic ward

##### Public title

Effect of Aloe Vera gel on prevention of pressure sore among patients hospitalized in orthopedic ward

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

The inclusion criteria will be: Lack of skin diseases (like psoriasis, fungal diseases; Vitiligo); patients over 18 years and below 65; patients diagnosed by a nurse as a 'risk for impaired skin integrity', by applying the Braden Scale for prediction of pressure ulcer risk showing a high risk or moderated risk (score under14); willingness to participate in the research; not having pressure ulcers; possibility of Continuity of orthopedics ward hospitalization ;being receptioned more than 24 hours in orthopedic ward and not being already admitted in another part; The lack of systemic disease, diabet, Bleeding from injury, heart failer, renal failer and advanced phase of cancer; Having a systolic blood pressure of 10 mm Hg or higher; not receiving vasoactive drugs; lack of drug addiction; temperature under 38.8; hemoglobin upper than 12. Exclusion criteria: The patient declining to take part in research; the patient death; hemoglobin reduction level during the study in men below 12 and in women below 10 mg /dl; receiving vasoactive drugs; anemia,hypotention, hyperthermia during the study.

## **Age**

From **77 years** old to **30 years** old

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **80**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Triple blinded

## **Blinding description**

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of the Arak University of Medical Sciences

##### **Street address**

Floor 3; Bldg Emam Mosaa Kazem; University of Medical Sciences Complex; Sq Basij; Sardasht

##### **City**

Arak

##### **Postal code**

3848176941

## **Approval date**

2016-05-23, 1395/03/03

## **Ethics committee reference number**

IR.ARAKMU.REC.1395.40

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Pressure Ulser

#### **ICD-10 code**

L89

#### **ICD-10 code description**

Decubitus ulcer and pressure area

## **Primary outcomes**

### **1**

#### **Description**

The incidence of pressure ulcers

#### **Timepoint**

The third day, seventh, tenth after intervention

#### **Method of measurement**

check list of daily erythema, temperature, edema and pain

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group :At first some pure Aloe Vera gel is tested on Inside of the forearm and in the absence of an allergic reaction, at a later stage pure Aloe Vera gel is applied twice a day (at 9a.m and 9 p.m) on the pressure areas (hip, sacrum and heel) for 10 days. And we wait for 2-1 minutes to have the gel absorbed. Under study areas are controlled on days 3, 7 and 10 in terms of presence or absence of symptoms of pressure ulcers based on the index means of pressure ulcers and scale of Braden risk of pressure ulcer.

#### **Category**

Prevention

### **2**

#### **Description**

control group: the researcher moisturizes the same areas by placebo (gel, water and starch) using an applicator and removes the material from the skin by a tissue. Sacrum, hip and heel are controlled on days 3, 7 and 10 in terms of presence or absence of symptoms of pressure ulcers based on the scale of pressure ulcers and scale of Braden risk of pressure ulcer.

#### **Category**

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Vali-Asr Hospital of Arak

**Full name of responsible person**

Fatemeh Mehrabi

**Street address**

School of Nursing and Midwifery; University Complex  
Payambar Azam; Sq Basij; Sardasht

**City**

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Arak University of  
Medical Sciences

**Street address**

Floor 3; Bldg Emam Mosaa Kazem; University of  
Medical Sciences Complex; Sq Basij; Sardasht

**City**

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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**

Arak University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Fatemeh Mehrabi

**Position**

MSc Student of Medical Surgical Nursing

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

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Davud Hekmat Pou

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## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*