Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

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

Protocol summary

Summary

This study intents 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)

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+98 86 3457 5029

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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

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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

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City
Arak

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
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Position
MSc Student of Medical Surgical Nursing

Other areas of specialty/work

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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