

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison between the effect of Aleo Vera and Olive Oil preventive dressing usage on pressure injury development in critically ill patients who admitted to intensive care unit (ICU) of Velayat Teaching Hospital, Qazvin.

Protocol summary

Study aim

Determining of the effect of Aleo Vera and Olive Oil preventive dressing usage on pressure ulcer development in critically ill patients who admitted to intensive care unit (ICU) of Velayat Teaching Hospital, Qazvin

Design

Three arm parallel group, non-randomized, single-blind, controlled clinical trial

Settings and conduct

The present clinical trial study was designed to compare the effect of Aloe vera gel and olive oil preventive dressings on the development of pressure injury. The research setting will be the intensive care unit (ICU) of Velayat Teaching Hospital, Qazvin. This study seeks to include all patients admitted to intensive care units (ICUs) as long as they meet the inclusion criteria. In this study, eligible patients will be divided into three groups: 1. Aloe vera, 2. Olive oil, and 3. Control.

Participants/Inclusion and exclusion criteria

Inclusion: the patient or his/her family's informed consent to participate in the study; aged above 18 years old. The absence of pressure injury on arrival at ICU. Patients with moderate to high risk based on the score they achieved from the Braden criterion at entry (score 14 and below). Exclusion criteria: pressure injury development within the first 12 hours after entering the ward. Conditions where the patient's position cannot be changed, such as patients with spinal cord injury. Drug sensitivity to Aleo Vera in group 1 and Olive oil in group 2 (according to patient or if sensitivity was observed in the study). Patient's death

Intervention groups

In this study, eligible patients will be divided into three groups: 1. Aloe vera, 2. Olive oil, and 3. Control.

Main outcome variables

Pressure ulcer development

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046008N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Ali Razaghpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3357 8340

Email address

alirazaghpoor@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of Aleo Vera and Olive Oil preventive dressing usage on pressure injury development in critically ill patients who admitted to intensive care unit (ICU) of Velayat Teaching Hospital, Qazvin.

Public title

The effect of Aleo Vera and Olive Oil preventive dressing usage on pressure injury development.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient or his/her family's informed consent to participate in the study. Aged above 18 years old. The absence of pressure injury on arrival at ICU. Patients with moderate to high risk based on the score they achieved from the Braden criterion at entry (score 14 and below).

Exclusion criteria:

Pressure injury development within the first 12 hours after entering the ward. Conditions where the patient's position cannot be changed, such as patients with spinal cord injury. Drug sensitivity to Aleo Vera in group 1 and Olive oil in group 2 (according to patient or if sensitivity was observed in the study). Patient's death

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

In this study, eligible patients will be divided into three groups by non-random sampling method using balls and bag method: 1. Aloe vera group, 2. Olive oil group, and 3. Control group. This process will be performed by a ward nurse who is unaware of the research.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences; Shahid Bahonar Boulevard; Qazvin.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.QUMS.REC.1398.109

Health conditions studied**1****Description of health condition studied**

Pressure injury

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes**1****Description**

Pressure injury

Timepoint

Twice, everyday for 7 day

Method of measurement

Pressure injury staging system

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The patients' skin is examined twice a day for 7 days and the sacrum area will be bandaged using an aloe vera gel preventive dressing. Regarding the dressing and the amount and percentage of the mentioned substances, it should be noted that the amount and percentage of the substance used is determined according to the recommendation of the manufacturer and the opinion of the pharmacologist, and the size of the gases is determined according to the

opinion of the pharmacologist; Thus, the preventive dressing consists of a simple gas measuring 5 cm² impregnated with 5 cc of aloe vera, which will be used in the anatomical region of the sacrum to prevent pressure injury. It should be noted that pure aloe vera gel (100%) will be supplied by Siegol company

Category

Treatment - Other

2

Description

Intervention group: The patients' skin is examined twice a day for 7 days and the sacrum area will be bandaged using an olive oil preventive dressing. Regarding the dressing and the amount and percentage of the mentioned substances, it should be noted that the amount and percentage of the substance used is determined according to the recommendation of the manufacturer and the opinion of the pharmacologist, and the size of the gases is determined according to the opinion of the pharmacologist; Thus, the preventive dressing consists of a simple gas measuring 5 cm² impregnated with 5 cc of olive oil, which will be used in the anatomical region of the sacrum to prevent pressure injury. It should be noted that pure olive oil (100%) will be supplied by Bahar company

Category

Treatment - Other

3

Description

Control group: Patients' skin will be examined twice a day for 7 days, using a preventative dressing without any special substance.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Ali Razaghpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Farnoosh Rashvand

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

SPSS file that includes raw data without participants
identity information

When the data will become available and for how long

after article publishing to one year after this

To whom data/document is available

medical science reserchers

Under which criteria data/document could be used

scientific

From where data/document is obtainable

correspondence author

What processes are involved for a request to access data/document

email to correspondence author

Comments