Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between effect of aloe vera and honey prophylactic dressings on the incidence of pressure injury among Elderly Patients

Protocol summary

Study aim
Determination of the effect of preventive dressing of Aloe vera and honey gel on the incidence of compression wound in patients admitted to the intensive care unit (ICU) of Qazvin vellayat hospital

Design
This study is a clinical trial with parallel groups. 30 samples in each group are included in the study. Considering the fact that we have three groups, 90 samples are being studied. Randomization: 90 balls are placed inside the bag, and the ball is numbered up to 30 first groups, 31 to 60 second group and 61-90 third group. With the arrival of each patient, an orb is pulled out and the patient is placed in the target group and the ball is pulled out of the bag.

Settings and conduct
For 7 days, twice a day, the patient is washed with normal saline in the sacrum area. Then, in the first group, the Aloe vera gel is used in the second group of honey, and in the third group the is used simple dressing gauze. We will not be blind in this study

Participants/Inclusion and exclusion criteria
Inclusion criteria: No pressure ulcer at the time of arrival of the patient to ICU, 2. Medium and high risk patients, based on the score that Bradan scored when entering the ICU section.3. Age over 60 years old exclusion criteria: 1. Absolute movement limits

Intervention groups
Intervention group: Use of Aloe vera gel in sacrum area and application of honey in sacrum area. Control group: Traditional sterile gas dressing

Main outcome variables
The rate of the patient's exposure to pressure injury

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190326043114N1**
Registration date: **2019-11-09, 1398/08/18**
Registration timing: **retrospective**

Last update: **2019-11-09, 1398/08/18**
Update count: **0**

Registration date
2019-11-09, 1398/08/18

Registrant information

Name
Amirhosein farzami

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-03, 1398/01/14

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between effect of aloe vera and honey prophylactic dressings on the incidence of pressure injury among Elderly Patients

Public title

effect of aloe vera and honey prophylactic dressings on the incidence of pressure injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

not having pressure ulcer at the time of admission to the ICU Patients with a high and medium risk score based on the Braden criterion at the start of the ICU (Score Bradden adjusted to 14 and lower). Age over 60 years old

Exclusion criteria:

There is an absolute motion limitation requested by the physician and prevents the patient from moving.

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

for random allocation in this study will be use Bowl and individual methods It will be placed 90 small beads in a non-transparent container On the beads, the number will be one to 90 labels. The numbers 1 to 30 belong to the AloeVera group and the numbers 31 to 60 belong to the honey group and the numbers 61 to 90 belong to the placebo group. After each patient is admitted to the intensive care unit, a bead will be randomly removed from the container. And determine which the patient will belong to, of the three groups And the nut will be removed and will not be returned to the container

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences.Qazvin. Shahid Bahonar Blvd.

City

qazvin

Province

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Postal code

31948183111

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.QUMS.REC.1397.403

Health conditions studied

1

Description of health condition studied

pressure ulcer

ICD-10 code

l89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes

1

Description

percentage of incidece pressure ulcer

Timepoint

Daily check up spot of medication use

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patient sacrum area is evaluated for 7 days, twice daily, for the onset of compression ulcers. In the absence of a pressure ulcer, the skin of the sacrum area is first washed with a normal saline solution. Then, 5 cc of the Aloe Vera gel is applied to the sacrum skin, and then a simple dressing gauze with 10 * 10 cm dimensions is placed on it and will be kept with a mattress glue on the skin.

Category

Prevention

2

Description

Intervention group 2: Sacrum area of the patient is evaluated for the duration of 7 days, twice daily, for the incidence of compression ulcers. In the absence of a pressure ulcer, the skin of the sacrum area is first washed with a normal saline solution. Then 5 cc of honey is rubbed into the skin of the sacrum area, and then a simple dressing gauze placed 10 x 10 cm in size and will

be kept firmly fixed on the skin with a mattress glue.

Category

Prevention

3

Description

Control group: The skin of the sacrum area of the patient will be examined twice a day by the nurse for the occurrence of pressure ulcers twice daily for a maximum of seven days.In the absence of pressure ulcer as soon as it enters the icu unit, the skin of the sacrum area is first washed and cleaned by the researcher with normal saline solution, and a simple dressing gas of 10 x 10 cm is applied on it and glued on. It will be fixed on the skin.glued

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Amirhoseinfarzami

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Taavon Square, 22 Bahman Blvd, Elahieh, Qazvin, Iran

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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

Private

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

Assistant Professor

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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Information will be published in the form of a paper
When the data will become available and for how long
After the end of the data collection
To whom data/document is available
There is no limit
Under which criteria data/document could be used
Any person or organization that needs to receive information can send the email to the person in charge of receiving the information
From where data/document is obtainable
Responsible person - Dr. Farnoosh Rashvand
What processes are involved for a request to access data/document
send mail
Comments