

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparative investigating of the Effect of Aloe Vera gel and Olive Oil on Incidence of pressure ulcer in patients Hospitalized in units of Aliebn-abitaleb Hospital, Rafsanjan 2019

Protocol summary

Study aim

determination of the Effect of Aloe Vera gel and Olive Oil on Incidence of pressure ulcer in patients Hospitalized

Design

controlled clinical trial with a parallel group design of 120 patients.triple blinded, randomized.

Settings and conduct

In this study 120 patients admitted to Ali Ibn Abi Talib Hospital wards of Rafsanjan will be selected based on inclusion criteria and will be divided into four groups (Aloe Vera-placebo, Olive-placebo, Olive-Aloe Vera and control group).. The selected patients will receive Aloe Vera gum, topical olive oil and two placebo for one week, and each 24 hours of skin care will be checked by the evaluator and the presence or absence of grade 1 to 4 ulcers in these areas will be recorded on the checklist. .

Participants/Inclusion and exclusion criteria

The inclusion criteria : 1- Inclination to participate in research 2. Age over 18 years 3. Braden score less than 14 4. Lack of diabetes 5. Lack of skin diseases 6. Lack of pressure ulcer beforehand 7. Having a systolic blood pressure of 10 mm Hg and above 8. Not having fever (Body temperature higher than 38/8) 9. Hemoglobin higher than 12 mg / dl 10. No history of allergy to olive oil and aloe vera gel and their products Exit criteria: 1- Not willing to continue participating in the study 2. Reduced hemoglobin levels 3. Reduced blood pressure to less than 100 mmHg 4. Hyperthermia during the study 5- Sensitization to olive oil, Aloe vera gel, placebo and any other medicine. 6. Transferring the patient to another center 7- Increase Braden Score to over 14 8. death

Intervention groups

Based on the inclusion criteria, 120 people are selected and divided into four groups. Of these, three groups A, B.C are recipients of substances, placebo and routine care, and D group as a control group only receives routine care.

Main outcome variables

Incidence of pressure ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N20**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

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Name of organization / entity

Rafsanjan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigating of the Effect of Aloe Vera gel and Olive Oil on Incidence of pressure ulcer in patients Hospitalized in units of Aliebn-abitaleb Hospital, Rafsanjan 2019

Public title

Comparative investigating of the Effect of Aloe Vera gel and Olive Oil on Incidence of pressure ulcer in patients Hospitalized

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclination to participate in research Age over 18 years Braden score less than 14 Lack of diabetes Lack of skin diseases (such as psoriasis, fungal disease) Lack of pressure ulcer beforehand Having a systolic blood pressure of 10 mm Hg and above Not having fever (Body temperature higher than 38/8) Hemoglobin higher than 12 mg / dl No history of allergy to olive oil and aloe vera gel and their products

Exclusion criteria:

Not willing to continue participating in the study Reduced hemoglobin levels during the study to less than 12 mg / dL in men and less than 10 in women Reduced blood pressure to less than 100 mmHg Hyperthermia (temperature higher than 38.8) during the study Sensitization to olive oil, Aloe vera gel, placebo and any other medicine. Transferring the patient to another care center Increase Braden Score to over 14 Patient's death

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the Braden criterion, people with a moderate and severe risk of pressure ulcer are identified. then, 120 people are selected for entry criteria. Subsequently, according to the random block method, people are divided into four groups of 30 with titles A, B, C, D. A {Aloe vera-Placebo group} B {olive oil - placebo group} C {Olive Oil - Aloe Vera group} D {control group}

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, the outcome assessor and the Data analyser are not aware of the type of substance used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Emam Ali Blv, Central Organization of the Central Organization of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7718174715

Approval date

2019-03-15, 1397/12/24

Ethics committee reference number

IR.RUMS.REC.1397.261

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

Pressure ulcer

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

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

Incidence or absence of pressure ulcers

Timepoint

Evaluate skin samples after using the ingredients every 24 hours for seven days

Method of measurement

check list of pressure ulcer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Each person in this group receives an Aloe vera gel on one side of his sacrum and iliac, and on the other side he receives a placebo (a lubricant gel) at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses.

Category

Prevention

2

Description

Intervention group: intervention group B: Each person in this group receives olive oil on one side of his sacrum and his iliac, and on the other side he receives a placebo (glycerin oil) at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses.

Category

Prevention

3

Description

Intervention group C: Each person in this group receives olive oil on one side of his sacrum and his iliac, and on the other side he receives Aloe Vera gel at 5 cc twice a day for seven days.in addition to he receives Routine care, involves changing the patient's position every 2 hours and using wavy mattresses.

Category

Prevention

4

Description

Control group: Group D: No intervention other than routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliebnabitaleb hospital of Rafsanjan

Full name of responsible person

Najmeh Ghasemirad

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Sponsors / Funding sources

1

Sponsor

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Tayebeh Mirzaei

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available