Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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Tayebeh Mirzaei

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 analyer 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

Street address
Jomhory street, Parastar blv

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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
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Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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