Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of the effect of Aloe Vera Gel, Olive oil and Compound Aloe Vera Gel- Olive oil on Prevention of pressure ulcer

Protocol summary

Study aim
The aim of the study is to determine the effect of Aloe Vera Gel and olive oil on Prevention of Pressure ulcer

Design
A clinical trial with a community-based, practice-oriented control group(intervention group 120, control group 40), with parallel groups, not blinding. Randomized random block method

Settings and conduct
The research sample size consists of At least 160 patients without pressure ulcer(intervention group 120, control group 40) in Imam Reza hospital in Kermanshah city in 2017-2019

Participants/Inclusion and exclusion criteria
Inclusion criteria:Consent of the physician and the patient to participate in the study,Insensitivity to Aloe vera and olive oil, no skin disease, cancer, diabetes, nervous and psychotic disorder and kidney failure, having aged over 18 years,Non-use of nitroglycerin, immunosuppressive drugs, lack of pressure ulcers,No bleeding, earn points equal to 14-6 from Braden scale, no addiction to drugs and alcohol. Exclusion criteria:Occurrence of pressure ulcer,Reduction of platelets and hemoglobin, reluctance to continue cooperation, need for any surgery,earn points more than 18 from Braden scale ,Administration of nitroglycerin and immunosuppressive drugs,

Intervention groups
The intervention in this study is using the Aloe Vera Gel، olive oil and Combination of olive oil and Aloe Vera Gel. There is no intervention in the control group .

Main outcome variables
Prevention of pressure ulcers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181105041563N4**
Registration date: **2019-01-01, 1397/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-01, 1397/10/11**
Update count: **0**

Registration date
2019-01-01, 1397/10/11

Registrant information

Name
Somayeh Mahdavikian

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
2018-06-22, 1397/04/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of the effect of Aloe Vera Gel, Olive oil and Compound Aloe Vera Gel- Olive oil on Prevention of pressure ulcer

Public title

Comparative evaluation of the effect of Aloe Vera Gel, Olive oil and Compound Aloe Vera Gel- Olive oil on Prevention of pressure ulcer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Consent of the physician and the patient to participate Insensitivity to Aloe vera and olive oil no skin disease, cancer, diabetes,nervous and psychotic disorder and kidney failure Non-use of nitroglycerin no addiction to drugs and alcohol earn points equal to 14-6 from Braden scale lack of pressure ulcer in order to NPUAP scale Non-use ofimmunosuppressive drugs having aged over 18 years No bleeding,

Exclusion criteria:

reluctance to continue cooperation earn points more than 18 from Braden scale Administration of nitroglycerin and immunosuppressive drugs, need for any surgery Reduction of platelets and hemoglobin, Occurrence of pressure ulcer in order to NPUAP scale

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified samples were entered into the study by accessible method and randomly divided into intervention groups (Aloe Vera Gel, olive oil and Combination of Aloe Vera Gel and olive oil) and control. Blocks were done as follows: To dressing groups with Aloe Vera Gel, sildenafil Ointment and Combination of Aloe Vera Gel and olive oil was assigned A ، B and C codes respectively, and the control group received D code. The study blocks were ABCD, ABDC, ACBD, ACDB, ADBC, ADCB, and the ABCD block was selected as the first block. Patients were assigned to Aloe Vera Gel, olive oil,Combination of Aloe Vera Gel and olive oil , and control groups, respectively, and this method continued until the samples were completed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.KUMS.REC.1396.477

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

prevention of pressure ulcer

Timepoint

At 8 o'clock in the morning, every other day, up to 30 days,

Method of measurement

braden and NPUAP scales

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group 1: The areas under pressure will be rubbed three times a day, with Aloe Vera gel for 30 days, at 8:00 am and these areas in every other day will be examined by Braden and NPUAP criteria up to 30 days. The brand of this gel is Aloe Vera gel and its scientific name is Aloe Barbadensis Miller.

Category

Other

2

Description
Intervention group: Group 2: The areas under pressure will be rubbed three times a day, with olive oil for 30 days, at 8:00 am and these areas in every other day will be examined by Braden and NPUAP criteria up to 30 days.
Category
Other

3

Description
Intervention group: Group 3: The areas under pressure will be rubbed three times a day, with a combination of Olive oil and Aloe Vera in 2: 3 ratio for 30 days, at 8:00 am and these areas in every other day will be examined by Braden and NPUAP criteria up to 30 days.
Category
Other

4

Description
Control group: Group 4: There is no intervention in the control group.The areas under pressure will be checked in every other day by Braden and NPUAP criteria up to 30 days.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Somayeh Mahdavikian
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Imam Reza hospital, Baghe Abrisham
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Behrooz Hamzeh
Street address
address Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran
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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
Vice chancellor for research, Kermanshah 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
Kermanshah School of Nursing and Midwifery
Full name of responsible person
Somayeh Mahdavikian
Position
Faculty Member
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable