

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Mahdavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

Email address

somayeh.mahdavian@kums.ac.ir

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 of immunosuppressive 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 Beheshti 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 Mahdavian

Street address

Imam Reza hospital, Baghe Abrisham

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kums.ac.ir

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 Beheshti Blv., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

676715987479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kkums.ac.ir

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 Mahdavian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Blv., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavian@kums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah School of Nursing and Midwifery

Full name of responsible person

Somayeh Mahdavian

Position

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+98 83 3816 2560

Email

Somayeh.Mahdavian@kums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah School of Nursing and Midwifery

Full name of responsible person

Somayeh Mahdavian

Position

Somayeh Mahdavian

Latest degree

Master

Other areas of specialty/work

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Phone

+98 83 3816 2560

Email

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Web page address**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