

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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

Kermanshah School of Nursing and Midwifery

**Full name of responsible person**

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Master

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**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

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**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