Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative evaluation of the effect of Aloe Vera Gel and Sildenafil ointment on Pressure ulcers in stage II

Protocol summary

Study aim
The aim of the study is to determine the effect of Aloe Vera Gel and Sildenafil ointment on Pressure ulcer

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

Settings and conduct
The research sample size consists of 120 patients with grade 2 pressure ulcer(intervention group 90, control group 30) in Imam Reza hospital in Kermanshah city in 2017

Participants/Inclusion and exclusion criteria
The inclusion criteria: Physician and patient satisfaction, Aloe vera and sildenafil susceptibility, No wound infection, No skin disease, Diabetes and kidney failure, Age over 18, No drug use The exclusion criteria: platelet loss, need for debridement, unwillingness to cooperate, need for surgery, bleeding and death

Intervention groups
The intervention in this study is using the Aloe Vera Gel(94%)، Ointment sildenafil citrate(.3%) and Combination of Sildenafil Citrate Ointment(.3%) and Aloe Vera Gel(94%).In the control group, the intervention is the use of Comfeel dressing. The wound will be checked by push-scale on days 1,3,7,14,21,30

Main outcome variables
Healing of pressure ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181105041563N1**
Registration date: **2018-12-05, 1397/09/14**
Registration timing: **registered_while_recruiting**
Last update: **2018-12-05, 1397/09/14**
Update count: **0**

Registration date
2018-12-05, 1397/09/14

Registrant information

Name
Somayeh Mahdavikian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3827 9394

Email address
somayeh.mahdavikian@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2019-01-21, 1397/11/01

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 and Sildenafil ointment on Pressure ulcers in stage II

Public title
Comparative of the effect of Aloe Vera Gel and Sildenafil ointment on Pressure ulcers in stage II

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent of the physician and the patient to participate in the study Insensitivity to Aloe vera and sildenafil The absence of any signs of wound infection skin disease, having aged over 18 years stage 2 of Starling scale Lack of bleeding earn points equal to 14-6 from Braden scale no addiction to drugs and alcohol no diabetes, and kidney failure

Exclusion criteria:

Reduction of platelets and hemoglobin need for debridement reluctance to continue cooperation need for any surgery bleeding death

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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, sildenafil Ointment and Combination of Aloe Vera Gel and Sildenafil Ointment) and control. Blocks were done as follows: To dressing groups with Aloe Vera Gel, sildenafil Ointment and Combination of Aloe Vera Gel and Sildenafil Ointment 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, sildenafil Ointment ,Combination of Aloe Vera Gel and Sildenafil Ointment , 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

2017-06-14, 1396/03/24

Ethics committee reference number

KUMS.REC.1396.145

Health conditions studied

1

Description of health condition studied

pressure ulcer

ICD-10 code

L89.1

ICD-10 code description

Stage II decubitus ulcer

Primary outcomes

1

Description

Healing of pressure ulcer

Timepoint

Day one, three, seven, fourteen, twenty one and thirty of the study

Method of measurement

push scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1, the wound will be dressed daily at 8:00 AM with Aloe Vera gel (94%) for 30 days, and will be checked on the days of 1,3,7,14,21,30 by push scale. The brand of this product is Aloe Vera gel and its scientific name Aloe barbadensis Miller. This herb is used as a gel and has antimicrobial and antioxidant effects, increased moisture, anti-inflammatory effects, inhibited thromboxane (an ulcer healing inhibitor), and increased blood flow to the wound site.

Category

Other

2

Description

In group 2, the ulcer will be dressed with sildenafil citrate (. 3%) ointment for 8 days, and will be dressed for 30

days, and will be checked in push-scale on days 1,3,7,14,21,30.The brands of this ointment are Viagra and Revatio. It has nitric oxide compounds, which have been shown to be effective in wound healing. These compounds stimulate cell proliferation, stimulate the activity of fibroblasts, collagen release, antimicrobial effect, antifungal, angiogenesis, increased blood flow to the site of injury and increase the secretion of the growth factor.

Category

Other

3

Description

In group 3, the ulcer, at 8 o'clock in the morning, with a combination of sildenafil citrate ointment(. 3%) and Aloe Vera gel (94%) will be dressed in a 3: 2 ratio for 30 days and will be examined by push-scale on days 1,3,7,14,21,30.

Category

Other

4

Description

Control group: In group 4, the ulcer, up to 30 days, every two days, at 8 o'clock, will be dressed with Hydrocolloid(Comfeel) and will be checked by push-scale on 1,3,7,14,21,30 days

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Somayeh Mahdavikian

Street address

Imam Reza hospital, Baghe abrisham

City

Kermanshah

Province

Kermanshah

Postal code

6715986479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavikian@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 Beheshty Blv., Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

676715987479

Phone

+98 83 3816 2560

Email

Somayeh.Mahdavikian@kums.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 Mahdavikian

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.Mahdavikian@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 Mahdavikian

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.Mahdavikian@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 Mahdavikian

Position
Faculty member

Latest degree
Master

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Email
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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