Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of topical Almond Oil on the prevention of bed sore in patients admitted to the Intensive Care Unit of Besat Hospital in Hamedan

Protocol summary

Study aim

Determination of the effect of almond oil on the prevention of bed sore in patients admitted to Intensive Care Units

Design

In this study, 86 patients with a Braden score of 18 or less were admitted to Besat Hospital in Hamadan. They were randomly assigned to three groups of placebo and intervention and control, and each group assigned a code.

Settings and conduct

The field of prevention is studying in the regions of the scapula, sacrum and heel of the patients admitted to ICU in Besat Hospital of Hamadan. Qualified individuals are randomly divided into 3 groups of control and intervention and placebo. Bleeding is done in the subjects studied and evaluated by the study. Patients do not know the type of substance they receive and the evaluator is not aware of the studied groups.

Participants/Inclusion and exclusion criteria

Entry Requirement: Acquiring Braden score, having no compression ulcers, aged over 18 and under the age of 85, the presence of skin problems, lack of susceptibility to almonds and their products, absence of diabetes history, hemodynamic status stability Non-compliance condition: Any allergy resulting from the use of almond oil, patient dissatisfaction or legal guardianship, patient transfer to another center, patient's death

Intervention groups

In this study, almond oil was used in intervention group pressure areas and placebo was used in placebo group pressure areas. The control group, along with the control and intervention group, receives only routine care.

Main outcome variables

Prevention of compression scars using almond oil in compression areas

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171128037657N1**
Registration date: **2017-12-11, 1396/09/20**
Registration timing: **prospective**

Last update: **2017-12-11, 1396/09/20**
Update count: **0**

Registration date

2017-12-11, 1396/09/20

Registrant information

Name

Sheller Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 9468

Email address

sh.amiri@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical Almond Oil on the prevention of bed sore in patients admitted to the Intensive Care Unit of Besat Hospital in Hamedan

Public title
Investigating Almond effect on bed sore
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gain score 18 or less according to Braden criterion Having at least 18 years of age and a maximum of 85 years
Exclusion criteria:
Dermatological allergy to drugs Having a bed sore Dissatisfaction with the patient or legal guardian Having a skin disease Receive any other topical ointment in the pressure areas Skin sensitivity to almond and its products
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization to balance the number of samples assigned to each of the groups studied, block sizes are randomly selected (blocks 6, 8, 10, and 14 each in an equal number of blocks per block). Is a tool for randomization of the SAS software. Allocation concealment, in the method used to execute a random sequence on the participants in the study, is said to be unclear before the assignment of the individual.
Blinding (investigator's opinion)
Double blinded
Blinding description
After obtaining informed consent, the patient is included in the study, the patient and the evaluator of the study are blind to the study. The oil and the placebo used in the treatment are poured into the same containers and used in the position. The evaluator has no knowledge of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Shahid Fahmida Blvd, Hamedan University of Medical Sciences, Faculty of Nursing and Midwifery
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Approval date
2017-12-26, 1396/10/05
Ethics committee reference number
IR.UMSHA.REC.1396.573

Health conditions studied

1

Description of health condition studied
Bedsore
ICD-10 code
L89.00
ICD-10 code description
Pressure ulcer of unspecified elbow

Primary outcomes

1

Description
Percentage of people with bed sore.
Timepoint
Daily review of the site for compression injuries for 7 days
Method of measurement
The National Pressure Ulcer Advisory Panel (NPUAP) is used.

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: This group receives brandy sweet almond oil on daily basis in the scapula, sacrum and heel areas. Almond oil is used daily for one week in these areas, and the daily assessment of the sites is done in terms of changes and changes.
Category
Prevention

2

Description
Second intervention group: A group in which daily oral paraffin oil is administered daily for up to one week in pressure-sensitive areas and is evaluated daily.
Category
Prevention

3

Description
Control group: In this group, only the usual care of the area, which includes changing the position of every three hours and the mattress, is applied to the next two groups, and is performed daily for one week.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Sheller Amiri
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Hamadan Province, Hamedan, District 2, Motahari Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saed Bashiri
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Shahid Fahmideh Blvd., Faculty of Nursing and Midwifery
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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
Hamedan University of Medical Sciences
Proportion provided by this source
80
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
Hamedan University of Medical Sciences
Full name of responsible person
Sheller Amiri
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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