Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of pistachio cream on grade one pressure ulcers in patients admitted to Ali Ebn Abitaleb Hospital.

Protocol summary

Study aim
Determining the effect of pistachio shell cream on the healing process of grade one pressure ulcers in patients admitted to Ali Ebn Abitaleb Hospital.

Design
A clinical trial with a control group, a parallel groups study with randomized minimization.

Settings and conduct
The research community in this clinical trial is the patients admitted to the intensive care unit of Ali Ebn Abitaleb Hospital of Rafsanjan. Patients who remain within the inclusion criteria are randomized into two groups. Pistachio cream and physiological serum are used to wash the wound in the participants of the intervention and control groups, respectively

Participants/Inclusion and exclusion criteria
All patients with stage one pressure ulcers were admitted to the ICU of Ali bin Abi Talib Rafsanjan Hospital in 2023. Non-entry conditions: People who have pressure ulcers of the second degree or higher

Intervention groups
Intervention group:Daily for seven days, after changing the body position and washing the wound with physiological serum, pistachio skin extract is applied with a thickness of (2-3) mm for intervention group participants. For control group participants, routine care includes changing the body position every 2-3 hours and daily washing the wound with physiological serum, is done.

Main outcome variables
Size of pressure wounds

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211128053199N2**
Registration date: **2023-08-25, 1402/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-25, 1402/06/03**
Update count: **0**

Registration date
2023-08-25, 1402/06/03

Registrant information

Name
Mahin Ghiyasi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-04, 1402/02/14

Expected recruitment end date
2024-05-03, 1403/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of pistachio cream on grade one pressure ulcers in patients admitted to Ali Ebn Abitaleb Hospital.

Public title
The effect of pistachio cream on grade one pressure ulcers in hospitalized patients.

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Immobile patients Moderate to severe loss of consciousness (Glasgow Coma Scale<8) Not having diabetes (based on the patient's medical history) Absence of skin disorders such as dermatitis Not taking corticosteroid drugs
Exclusion criteria:
Patients who have second degree pressure and higher
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants of the intervention and control groups are first selected among the intensive care unit patients with grade one pressure ulcers, using the convenience sampling method with the sample size of 35 participants. Then they are classified based on body mass index, (BMI ≤25 and BMI>25) and age (20-40 years, 41-60 years, 61-90 years). The first participant is randomized in the intervention or control group. Next participants enter the group with lower total BMI.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences (RUMS)
Street address
Emam Ali Blvd,Rafsanjan City
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Approval date
2022-04-12, 1401/01/23
Ethics committee reference number
IR.RUMS.REC.1401.008

Health conditions studied

1

Description of health condition studied
Pressure Ulcer
ICD-10 code
L89
ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Type 1 pressure ulcer
Timepoint
In both groups, three days after the intervention and one week later
Method of measurement
Wound healing process using the PUSH scale(PUSH) Pressure Ulcer Scale for Healing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To measure the size of the wound, the largest longitudinal and transverse diameter of the wound (using a caliper with an accuracy of one millimeter) is measured and multiplied together, and the size of the wound is recorded in square centimeters. The amount of wound secretions with the factors score zero: no exudation, score one: low exudation (the sterile gauze was not wet), score two: moderate exudation (one sterile gauze was wet) and score three: high exudation (2 gauzes were wet). And the degree of tissue improvement based on the first degree: epithelial tissue, second degree: granular tissue, third degree: progenitor tissue, and the fourth degree of necrotic tissue. The highest score in Posh system is 17 and the lowest score is 3. Lower scores indicate low severity and higher scores indicate greater severity of the wound. Then, the recorded size is scored based on the PUSH scale and considering that the first stage pressure ulcer has no exudate and tissue disorder, these two items are assigned a score of zero. Each time the scores are compared and the healing process of the wound is determined based on it, and after allocating people to groups, the intervention will be implemented by the main researcher. The green and fresh skin of the ripe Uhdi pistachio variety is separated by hand and dried in the

shade and at room temperature. Then the dried skin is ground and turned into powder. Finally, 150 grams of this powder is soaked in 600 ml of hydroethanolic solution for 96 hours at room temperature. After filtering with a cloth and then Whatman No. 1 filter paper, the extract solution under the filter is dried in an oven at a temperature of 40 °C. The obtained dry extract is kept at -20°C until consumption. It should be mentioned that the formulation is done in clean conditions by Barij Essans Daru Company in Kashan. In the intervention group, daily and for seven days after changing the position and washing the wound with physiological serum, pistachio skin extract with a thickness of (2-3) mm was applied to the wound using a sterile abslang and covered with a sterile gauze. can be In order to ensure that the patient is not allergic to pistachio skin extract, before the intervention, a layer of this extract will be rubbed on the inner part of the patient's arm and the patient's reaction will be checked within 30 minutes after use.

Category

Prevention

2

Description

Control group: In the control group, routine care includes changing the position every 2-3 hours and washing with physiological serum daily.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib Hospital

Full name of responsible person

Ali Nakhei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mahin Ghiyasi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
It will be available for researchers working in academic and scientific institutions, or people who are also working in industry can apply for them.

Under which criteria data/document could be used
It will be available for researchers working in academic and scientific institutions, or people who are also working in the industry can apply for them.

From where data/document is obtainable
For information, people can contact the responsible author by calling 09103131606 and by e-mail at mahinghiyasi.nurse@gmail.com and at the address of Rafsanjan, Nurse Street, Nursing School.

What processes are involved for a request to access data/document
Whenever a person requests information, she can communicate with the email and contact number, and she will receive the information after 24 hours.

Comments