

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### 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.

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

Update count: **0**

#### Registration date

2023-08-25, 1402/06/03

#### Design

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

#### Registrant information

##### Name

Mahin Ghiyasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3418 2587

##### Email address

mahinghiyasi.nurse@gmail.com

#### 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

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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

#### 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

#### 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.

#### Scientific title

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

#### Main outcome variables

Size of pressure wounds

#### Public title

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211128053199N2**

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

## 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 Uhd 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

##### Street address

Emam Ali Blvd.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3428 0000

##### Email

alinakhei77@yahoo.com

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Reza Vaziri

#### Street address

Emam Ali Blvd

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718796755

#### Phone

+98 34 3428 0041

#### Email

rvazirinejad@yahoo.co.uk

#### 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

Nursery

##### Street address

Parastar Blvd

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3428 0000

##### Email

mahinghiyasi.nurse@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Fateme khoshoei

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Parastar Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3428 0000

**Email**

fatemekhoshoei8@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Heidarzadeh Azam

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Parastar Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3428 0000

**Email**

heidarzadehazam@yahoo.com

**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**