

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Bitter almonds and Olive oil on the prevention of pressure ulcers in intensive Care units Patient

#### Protocol summary

##### Study aim

The effect use of olive oil and bitter almond oil on Areas under pressure of the skin, on predicting the symptoms of compression ulcers in ICU (Hospitals of Kerman University of Medical Sciences in 2018

##### Design

A clinical trial, the research community is patients admitted to special sectors of hospitals affiliated to Kerman University of Medical Sciences. The research sample is 96 patients divided in to three groups In the form of randomized blocks

##### Settings and conduct

The researcher is referring to the in hospitals of Kerman University of Medical Sciences. Available samples are selected according to inclusion and exclusion criteria, and they are randomly assigned to 3 groups. After selecting the samples, the demographic information questionnaire and the selected patients will be monitored every 24 hours for 2 weeks.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Having a Foley catheter.Having a Norton benchmark less than 16 Exit criteria: Dissatisfaction with Ghayumin.Observe any skin symptoms Having skin problems.The presence of allergens to bitter Almond and olive oil. Having a compression ulcer.Having diabetes

##### Intervention groups

In the First intervention group: of Olive oil , In addition to the usual treatments for the section's implementation used.In the Second intervention group: of bitter almond oil , In addition to the usual treatments for the section's implementation used.

##### Main outcome variables

Pressure ulcer

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160914029817N8**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **prospective**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

#### Registration date

2018-12-29, 1397/10/08

#### Registrant information

##### Name

Esmat Nuhi

##### Name of organization / entity

Kerman University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5220

##### Email address

e\_nuhi@kmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-02-14, 1397/11/25

#### Expected recruitment end date

2019-06-15, 1398/03/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Bitter almonds and Olive oil on the prevention of pressure ulcers in intensive Care units Patient

**Public title**

Investigating the effect of Olive and Bitter almonds on pressure ulcers

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having a Norton Criterion is less or equal 16 Having a Foley catheter

**Exclusion criteria:**

Dissatisfaction with Ghayumin having diabetes Having a pressure ulcer Observe any skin symptoms caused by drug allergy (rash, hives, redness, swelling). Having skin problems The presence of allergens to bitter bitter olives and their products

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 96

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block Randomize. The subjects are randomly assigned into three groups using software.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in the study do not know which oils are used on their skin.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical committee of kerman University of Medical Sciences

**Street address**

University of Medical Sciences, Haft Bagh Alavi, Kerman

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2018-11-21, 1397/08/30

**Ethics committee reference number**

IR.KMU.REC.1397.314

**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**

Create a pressure ulcer

**Timepoint**

Evaluation of pressure ulcers at the beginning of the study and Two weeks after the intervention

**Method of measurement**

Grading system for the substrate wound panel

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: First intervention group: Use of Olive oil from a reliable exir factory, which has been standardized on this product under laboratory conditions. This product has the standard code and Apple health mark of Iranian Food and Drug Administration and the register number is 10124.39. In addition to the usual treatments for the section's implementation that basically change the situation every two hours once and use the Wavy mat. Intervene in both groups for 2 weeks every 24 hours. Sacrum, Batex and Sacred Squares: 1 cc, Heels: 0/5cc, Batex:1/5cc Will Be Made

**Category**

Prevention

**2****Description**

Intervention group: Second intervention group: Use of bitter almond oil from a reliable factory of natural extract of Nowshad brand that has been prepared according to the standards approved by the Food and Drug Administration of Iran and has the and Apple health mark of Iranian Food and Drug Administration and the register

number is 1228208485. In addition to the usual treatments for the section's implementation that basically change the situation every two hours once and use the Wavy mat. Intervene in both groups for 2 weeks every 24 hours. Sacrum, Batex and Sacred Squares: 1 cc, Heels: 0/5cc, Batex:1/5cc Will Be Made.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shafa Hospital

**Full name of responsible person**

Shohreh Saljoghiyan

**Street address**

Shafa Medical Education Center, Kosar Blvd, Kerman

**City**

Kerman

**Province**

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**Fax****Email**

shafahospital@kmu.ac.ir

**Web page address**

htt://sh.kmu.ac.ir

**2****Recruitment center****Name of recruitment center**

Afzalipour Hospital

**Full name of responsible person**

Shohreh Saljoghiyan

**Street address**

Imam Khomeini highway, Kerman

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**3****Recruitment center****Name of recruitment center**

Shahid Bahonar Hospital

**Full name of responsible person**

Shohreh Saljoghiyan

**Street address**

Gharani St, Valiasr intersection, Kerman

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Kerman

**Province**

Kerman

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bahonarhospital@kmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Abbas pardakhty

**Street address**

Research Management, Deputy of research and technology, Ibn Sina St., Tahmasebad Square, Kerman

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kerman

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abpardakhty@kmu.ac.ir

**Web page address**

htt://vcrt.kmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Shohreh Saljoghian

**Position**

Master of Internal Surgery Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Razi Nursing and Midwifery Faculty, Kerman  
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**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Shohreh Saljoghian

**Position**

Master of Medical Surgery Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

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

Kerman University of Medical Sciences

**Full name of responsible person**

Smat nohi

**Position**

Ph.D. in Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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Medical Sciences, beginning of the Haft BaghAlavi  
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**Fax****Email****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