

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effect of Massage of Olive Oil and Sweet Almond on prevention of Bed Sore in Hospitalized Patients

#### Protocol summary

##### Study aim

Determination of the effect of olive oil and sweet almond oil on the prevention of bed sore

##### Design

A randomized clinical trial study was conducted in three groups (control and two test groups), with parallel, double blind, randomized groups

##### Settings and conduct

The sample size will be 90 patients whom randomly assigned to three groups (two intervention groups and one control group). Given that sweet almond oil and olive oil are odorless, but they are somewhat different in terms of concentration and color. Therefore, researcher blindness and researcher assistance will not be possible. However, in the case of research samples and the person analyzing the data, blinding information will be applied.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients without bed ulcer;  
exclusion criteria: Patient dissatisfaction with collaboration in the research.

##### Intervention groups

The method of intervention will be: every day, 1-3 ml of olive oil (first intervention group) or sweet almonds (second intervention group) we used in order for gently massage in the area like ears, scapula, spinal cord, lumbar, baettecks, cilia and sacrum, elbows, Heel and ankles. The control group too, received the nursing care like change position every 2 hours, and using wavy mattress (routine nursing care in the ward). the incidence of bed sore and its grades will be investigated within one week after using these two oils.

##### Main outcome variables

The primary outcome is the percentage of people with bed sores.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170124032147N4**

Registration date: **2018-05-14, 1397/02/24**

Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**

Update count: **0**

#### Registration date

2018-05-14, 1397/02/24

#### Registrant information

##### Name

Bahareh Ghafourzadeh Toomatari

##### Name of organization / entity

Tehran university of medical scienc, School of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6692 7171

##### Email address

b-ghafourzadeh@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Research Deputy

#### Expected recruitment start date

2017-06-22, 1396/04/01

#### Expected recruitment end date

2017-09-21, 1396/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the Effect of Massage of Olive Oil and

Sweet Almond on prevention of Bed Sore in Hospitalized Patients

### Public title

The Effect of Olive Oil and Sweet Almonds on the prevention of Bed Sore

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients without Bed Sore Inability to movement or to move only with an instrument

#### Exclusion criteria:

The possibility of any susceptibility to the use of Olive Oil or SweetAlmond oil Patient dissatisfaction with collaboration in the research

### Age

From **42 years** old to **93 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The research samples were randomly assigned to the six-block questionnaire, which were performed by the software. Sixth permutations were determined using the three letters A for the control group, the letter B for the intervention group with olive oil and the letter C for the intervention group with sweet almond oil, and using the randomized method, six permutations in the triple groups were chosen.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

It should be noted that sweet almonds and olive oil were odorless, but they have differences in their concentration and color, so blindness of researcher impossible. but these oils were placed in the dark bottle, so the patients were blindness. In this study double blindness (patients and analyzer the data ) were take place.

### Placebo

Not used

### Assignment

Parallel

### Other design features

To Randomize the method of enclosed envelopes used.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

(Nusrat East) Dr Mirkhani Ave., Tohid Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

##### Approval date

2017-06-19, 1396/03/29

##### Ethics committee reference number

IR.TUMS.FNM.REC.1396.2687

## Health conditions studied

### 1

#### Description of health condition studied

Bed sore

#### ICD-10 code

L89.9

#### ICD-10 code description

Pressure ulcer of unspecified site

## Primary outcomes

### 1

#### Description

The percentage of people with bed sore in Braden questionnaire

#### Timepoint

Before the intervention begins, every 24 hours for one week, immediately after the intervention

#### Method of measurement

Braden International Standard (Standard Instrument)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: The method of intervention were done as: every day, 1-3 ml of olive oil ( was made by Exir company) we used in order for gently massage in the area like ears, scapula, spinal cord, lumbar, baettecks, cilia and sacrum, elbows , Heel and ankles. In deed the patients gave the nursing care like change position every 2 hours, and using wavy mattress (routine nursing care in the ward). Then, the incidence of bed sore and its grades will be investigated within one week after using this oil.

## Category

Prevention

## 2

### Description

Second intervention group: The method of intervention were done as: every day, 1-3 ml of sweet almond oil (was made by Barij essence) we used in order for gently massage in the area like ears, scapula, spinal cord, lumbar, baettecks, cilia and sacrum, elbows , Heel and ankles. In deed the patients gave the nursing care like change position every 2 hours, and using wavy mattress (routine nursing care in the ward). Then, the incidence of bed sore and its grades will be investigated within one week after using this oil.

### Category

Prevention

## 3

### Description

control group: The control group, just giving the routine treatment such as, change position every 2 hours, and using wavy mattress. Then, the incidence of bed sore and its grades will be investigated within one week.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Jafar Sadeq hospital (AS)

#### Full name of responsible person

Zainab Islami Hassan Abadi

#### Street address

Imam Jafar Sadeq hospital (AS), Square Veteran, Basij Boulevard

#### City

Maybe

#### Province

Yazd

#### Postal code

8961977138

#### Phone

+98 35 3235 1200

#### Email

ali.rahimy67@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Massoud Younesian

#### Street address

Beginning of Ghods Ave., Keshavarz Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733171

#### Phone

+98 35 3232 9608

#### Email

ali.rahimy67@gmail.com

#### Grant name

-

#### Grant code / Reference number

-

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

Yes

#### Title of funding source

Tehran 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

Faculty of Nursing and Midwifery Medical Sciences of Tehran

#### Full name of responsible person

Zainab Islami Hassan Abadi

#### Position

Master's degree in Internal Surgery Nursing

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nursery

#### Street address

(Nusrat East) Dr. Mirmohani Ave., Tohid Square

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733171

#### Phone

+98 35 3232 9608

#### Fax

#### Email

b-ghafourzadeh@razi.tums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Faculty of Nursing and Midwifery Tehran University of Medical Sciences

**Full name of responsible person**

Zainab Islami Hassan Abadi

**Position**

Master's degree in Internal Surgery Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

(Nusrat East) Dr. Mirmohani Ave., Tohid Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 35 3232 9608

**Fax****Email**

b-ghafourzadeh@razi.tums.ac.ir

**Web page address****Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

(Nusrat East) Dr. Mirmohani Ave., Tohid Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 35 3232 9608

**Fax****Email**

b-ghafourzadeh@razi.tums.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**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**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

## Person responsible for updating data

### Contact

**Name of organization / entity**

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

**Full name of responsible person**

Zainab Islami Hassan Abadi

**Position**

Master's degree in Internal Surgery Nursing