

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effect of olive oil and sesame oil on the prevention of pressure ulcers in ICU patients.

#### Protocol summary

##### Study aim

Comparison of the effect of olive oil and sesame oil in the prevention of pressure ulcers

##### Design

Clinical trial without control group, with parallel groups, triple blind, randomized, phase 2 on 60 patients, the random function of Excel software was used for randomization.

##### Settings and conduct

The place of study: The intensive care unit (ICU) was from Amir Al-Momenin; Valiasr; hospitals in Arak; Type of blinding: Three blind; How to blind: Use of stained glass and odorless oils

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : ;Willingness to participate in research ;Age over 18 years and under 65 years ;Braden score below 14 ;Probability of continuing hospitalization in the ICU ;Less than 24 hours have passed since their admission to the ICU and they have not been admitted to another ward before ;Having a systolic blood pressure of 10 mm Hg and above ;Have a hemoglobin of 12 or higher  
Criteria for not entering: ;Having skin diseases ;Having pressure sores on admission ;Systemic diseases such as diabetes, bleeding from the site of injury, heart failure, kidney failure and advanced stage cancer ;Receiving vasoactive drugs ;Having a fever (body temperature above 38.8)

##### Intervention groups

Intervention group 1(NA): In this group, the consumption of olive oil on the pressurized areas that have been previously examined by Braden score and have a result below 14 is rubbed and the progress of the lesion is evaluated. Intervention group 2 (SA): In this group, sesame oil is rubbed on the pressure areas that have been previously examined with the Braden score and the lesion is under 14 and the progression of the lesion is evaluated and the increase in pressure and its speed of healing is compared with the intervention group 1.

##### Main outcome variables

pressure ulcer

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220110053683N1**

Registration date: **2022-04-05, 1401/01/16**

Registration timing: **prospective**

Last update: **2022-04-05, 1401/01/16**

Update count: **0**

##### Registration date

2022-04-05, 1401/01/16

##### Registrant information

##### Name

Parsa Ahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3631 3922

##### Email address

parsawe@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-09, 1401/01/20

##### Expected recruitment end date

2022-07-11, 1401/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of the effect of olive oil and sesame oil on the prevention of pressure ulcers in ICU patients.

### Public title

Comparison of the effect of olive oil and sesame oil on prevention of pressure ulcer

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Willingness to participate in research Age over 18 years and under 65 years Patients who are at moderate to severe risk of bed sores and score less than 14 according to the nurse's diagnosis and based on the scaling of the removal tool Probability of continuing hospitalization in the ICU Less than 24 hours have passed since their admission to the ICU and they have not been admitted to another ward before Having a systolic blood pressure of 10 mm Hg and above Have a hemoglobin of 12 or higher.

#### Exclusion criteria:

have Skin diseases (such as psoriasis, fungal infections, fleas and ticks) Having a pressure sore at the time of admission Systemic diseases such as diabetes, bleeding from the site of injury, heart failure, kidney failure and advanced stage cancer Receiving vasoactive drugs Having a fever (body temperature above 38.8)

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Care provider
- Data analyser

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In simple random sampling, each element of the target community has an equal chance of being selected. In this method, the required persons or objects are randomly selected from the list of statistical population that has been numbered and prepared for this purpose. In our study, the random number table method will be used and we will move from right to left horizontally. We will place odd numbers in intervention group 1 and even numbers in intervention group 2, then start by entering each of the samples with the conditions for inclusion in the study.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

In this study, the nurse - the person analyzing the statistical data - the patient himself will be blinded. To blind the nurse, two groups of glass containers (a - b) of

the same color are used for which olive and sesame oil are inseparable. Also, sesame and odorless olive oil made by Barij Essential Oil Company are used. To blind the person analyzing the statistical data, the information of the two groups with the symbols A and B, without mentioning which type of oil was used in each group, will be provided to the statistical data analyzer. In order to blind patients, the necessary explanations will be given at the beginning of the research (In this research, two types of oils are used and you will be randomly placed in one of these two groups without knowing it).

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

second partition, second floor , Vice Chancellor for Research and Technology, Arak University of Medical Sciences and Health Services, Payambar Azam (PBUH) University Complex, around Dr. Mehdi Charm Dooz Square, Dr. Mohammad Gharib Blvd, Sardasht region, Arak, Markazi

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

##### Approval date

2022-03-06, 1400/12/15

##### Ethics committee reference number

IR.ARAKMU.REC.1400.341

## 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

Prevention of pressure ulcers

### Timepoint

at the start of research and day 3 - 7

### Method of measurement

Braden score

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group 1: Admission will be assessed with Braden instrument, and those with a score below 14 who are at moderate to severe risk of bed sore will be included in the study. Then, on a daily basis, pressure ulcer prevention methods, such as changing position at least every two hours, using small pillows between the legs or heels to remove and reduce pressure, controlling urinary incontinence, and using absorbent pads and cleansing the skin (infection) is routinely performed for patients. The researcher first tests some sesame oil on the inner area of the forearm and if there is no allergic reaction, in the next steps twice a day (9-21 hours), 2-3 cc on pressure points (hip, sacrum, heel) is rubbed and allowed 1-2 minutes to absorb for 7 days. Then the sacrum, hip and heel of both groups of patients will be assessed on days 3 and 7 (based on previous studies as a cut point) in terms of incidence of pressure ulcer.

### Category

Prevention

## 2

### Description

Intervention group 2: Admission will be assessed with Braden instrument, and those with a score below 14 who are at moderate to severe risk of bed sore will be included in the study. Then, on a daily basis, pressure ulcer prevention methods, such as changing position at least every two hours, using small pillows between the legs or heels to remove and reduce pressure, controlling urinary incontinence, and using absorbent pads and cleansing the skin (infection) is routinely performed for patients. The researcher first tests some olive oil on the inner area of the forearm and if there is no allergic reaction, in the next steps twice a day (9-21 hours), 2-3 cc on pressure points (hip, sacrum, heel) is rubbed and allowed 1-2 minutes to absorb for 7 days. Then the sacrum, hip and heel of both groups of patients will be assessed on days 3 and 7 (based on previous studies as a cut point) in terms of incidence of pressure ulcer.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Valiasr Hospital

#### Full name of responsible person

Parsa Ahmadi

#### Street address

No. 54. Tobacco Town-University Town - Saqez - Kurdistan Province

#### City

arak

#### Province

Markazi

#### Postal code

6681473677

#### Phone

+98 918 212 1359

#### Email

parsawe@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

amir AL momenin hospital

#### Full name of responsible person

Parsa Ahmadi

#### Street address

No. 54. Tobacco Town-University Town - Saqez - Kurdistan Province

#### City

arak

#### Province

Markazi

#### Postal code

6681473677

#### Phone

+98 918 212 1359

#### Email

parsawe@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research and Technology of Arak University of Medical Sciences

#### Full name of responsible person

Alireza Kamali

#### Street address

second floor , Vice Chancellor for Research and Technology, Arak University of Medical Sciences and Health Services, Payambar Azam (PBUH) University Complex, around Dr. Mehdi charm Dooz Square, Dr. Mohammad Gharib Blvd, Sardasht region , Arak city , Markazi province.

#### City

Arak  
**Province**  
Markazi  
**Postal code**  
3848176341  
**Phone**  
+98 86 3417 3639  
**Email**  
research@arakmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor for Research and Technology of Arak 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**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Parsa Ahmadi  
**Position**  
nursing student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 54, Dokhania town, Daneshgah town, Saqqez  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
6681473677  
**Phone**  
+98 87 3631 3922  
**Email**  
parsawe@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**

fatemeh mehrabi  
**Position**  
Faculty member of Arak University of Medical Sciences  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
University Complex of the Great Prophet. sardasht .  
Arak  
**City**  
arak  
**Province**  
Markazi  
**Postal code**  
۳۸۱۹۶۹۳۳۴۰  
**Phone**  
+98 86 3417 3505  
**Email**  
fmehrabi1392@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Parsa Ahmadi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
No. 54, Dokhania town, Daneshgah town, Saqqez  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
6681473677  
**Phone**  
+98 86 3631 3922  
**Fax**  
**Email**  
Parsawe@gmail.com

## 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