

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topical application of black seed oil on the prevention of bedsores in patients admitted to the intensive care unit

Protocol summary

Study aim

Determining the effect of topical application of black seed oil on the prevention of bedsores in patients admitted to the ICU

Design

A clinical trial with a control group, parallel, not blinded, randomized, on 72 patients who were selected by available methods and Will be allocated into two groups of intervention and control by the Block randomization method. by Using non-transparent envelopes sealed with random sequences that the lids of the letter envelopes are glued and placed inside a box, respectively. based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Settings and conduct

Patients admitted to the intensive care unit of Imam Sadegh (AS) Hospital in Hashtgerd are selected by available methods and are randomly divided into two groups. For the control group, only the wavy mattress and changing the position will be used every two hours. But for the intervention group, in addition to the wavy mattress and changing the position every two hours, daily, 1-3 cc of the black seed oil is rubbed on the prone areas of bed sores for 7 days, then the results are compared in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients, Being between 18 and 75 years old, Not participating in similar research projects in the last six months, and Stable hemodynamic status. Non-entry conditions include bedsores, diabetes, and a history of allergy to black seed oil.

Intervention groups

Intervention group: In this group, in addition to the wavy mattress and change Positions every two hours, 1-3 cc of the black seed oil is rubbed on the Susceptible areas of bed sores for 7 days. Control group: In this group, only the wavy mattress and change Positions every two hours

will be used.

Main outcome variables

bedsores

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210317050732N1**

Registration date: **2021-05-15, 1400/02/25**

Registration timing: **prospective**

Last update: **2021-05-15, 1400/02/25**

Update count: **0**

Registration date

2021-05-15, 1400/02/25

Registrant information

Name

Azam Maboudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2200 6660

Email address

maboodiazam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of topical application of black seed oil on the prevention of bedsores in patients admitted to the intensive care unit

Public title
The effect of topical application of black seed oil on the prevention of bedsores

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients admitted to the intensive care unit Stable hemodynamic status Not participating in similar research projects in the last six months Being between 18 and 75 years old
Exclusion criteria:
Having bed sore having diabetes Allergy to black seed oil

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method will initially be available; The samples will then be placed in quadruple blocks by block random sampling. The blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment, we will have 4 blocks (including 2 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the

assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran Islamic Azad University of Medical Sciences
Street address
Islamic Azad University Medical Sciences of Tehran, Khaghani street, Shariati Street
City
Tehran
Province
Tehran
Postal code
1916893813

Approval date
2021-03-15, 1399/12/25

Ethics committee reference number
IR.IAU.TMU.REC.1399.571

Health conditions studied

1

Description of health condition studied
Bed sore

ICD-10 code
L89

ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Bed sore

Timepoint
Before the intervention and 7 days after the intervention

Method of measurement
The Braden Scale for Predicting Pressure Ulcer Risk

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to the wavy mattress and change Positions every two hours, 1-3 cc of the black seed oil(With a concentration of 100% made in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences in Good laboratory Practice=GLP) is rubbed on the Susceptible areas of bed sores for 7 days.

Category

Prevention

2

Description

Control group: In this group, only the wavy mattress and change Positions every two hours will be used.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sadegh (AS) Hospital of Hashtgerd

Full name of responsible person

Azam Maboudi

Street address

Next to Madar Park , Ayatollah Khamenei Blvd,
Hashtgerd city , Alborz province

City

Hashtgerd

Province

Alborz

Postal code

3149779453

Phone

+98 26 4421 0925

Email

Emamjafarsadegh@abzums.ac.ir

Web page address

<https://emamjafarsadegh.abzums.ac.ir/fa-IR/emamjafarsadegh.abzums.ac/8841/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Naghipour

Street address

Islamic Azad University Medical Sciences of Tehran,
Khaghani street, Shariati Street

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

mnaghipour@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Azam Maboudi

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Islamic Azad University Medical Sciences of Tehran,
Khaghani street, Shariati Street

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

maboodiazam@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zohreh Parsayekta

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Islamic Azad University Medical Sciences of Tehran,

Khaghani street, Shariati Street

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

Zparsa@tums.ac.ir

Islamic Azad University Medical Sciences of Tehran,

Khaghani street, Shariati Street

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

maboodiazam@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

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Azam Maboudi

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

Street address