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 bedsore 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

Bedsore

ICD-10 code

L89

ICD-10 code description

Pressure ulcer

Primary outcomes

1

Description

Bedsore

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
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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
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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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Zohreh Parsayekta

Position
Professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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