

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of fish oil, olive oil and honey on the prevention of bed sore in patient admitted to intensive care unit

Protocol summary

Study aim

The comparison of fish oil, olive oil and honey on the prevention of bed sore in patient admitted to intensive care unit

Design

This study will be a clinical trial with a control group, randomized, with parallel and blind groups.

Settings and conduct

one hundred (100) patients admitted to intensive care unit and prone to bed sore selected by a purposive sampling and randomly will be divide into three experimental and one control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients admitted to intensive care unit and prone to bed sore, having 20-60 years old, no sensitized to fish oil, olive oil or honey. exclusion criteria: having ulcer or active infection that need to intravenous antibiotics, take medications that may cause wounds Such as immunosuppressions and corticosteroids, Transferring a patient to another health facility or patient's death.

Intervention groups

"Intervention group1: After washing the heel of the patients is prone to bed sore, it will be dressed for a week with 4 cc of fish oil and at the end of the week it will be evaluated, 2:After washing the heel of the patients is prone to bed sore, it will be dressed for a week with 4 cc of olive oil and at the end of the week it will be evaluated,3: After washing the heel of the patients is prone to bed sore, it will be dressed for a week with 5 cc of honey and at the end of the week it will be evaluated" "Control group receive routine cares will include the change position every 2 hours and use of wavy mattress". All intervention groups will also receive routine care.

Main outcome variables

ulcer intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180227038885N1**

Registration date: **2018-08-03, 1397/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Maryam Khastavaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 8884

Email address

maryam.khastavaneh@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-31, 1397/03/10

Expected recruitment end date

2018-12-01, 1397/09/10

Actual recruitment start date

2018-06-05, 1397/03/15

Actual recruitment end date

2018-12-06, 1397/09/15

Trial completion date

empty

Scientific title

The comparison of fish oil, olive oil and honey on the prevention of bed sore in patient admitted to intensive care unit

Public title

The comparison of fish oil, olive oil and honey of bed sore

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients susceptible to bed sore based on Braden scale having 20-60 years old Do not Sensitization to fish oil, olive oil or honey

Exclusion criteria:

having ulcer or active infection that need to intravenous antibiotic use of drugs that may cause wounding, such as immunosuppressives and corticosteroids

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be allocated randomly by block assignment between the four groups.

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

Ethic committee of Yasuj University of Medical Sciences

Street address

Shahid Motahari Blvd

City

Yasuj

Province

Kohgiluyeh-va-Boyrhmad

Postal code

7591741417

Approval date

2018-02-17, 1396/11/28

Ethics committee reference number

IR.yums.REC.1396.69

Health conditions studied

1

Description of health condition studied

pressure ulcer

ICD-10 code

L89.600

ICD-10 code description

Pressure ulcer of unspecified heel, unstageable

Primary outcomes

1

Description

ulcer intensity of heel based on Braden scale

Timepoint

severe heel ulcer is evaluated before the intervention and one week after the end of the intervention. The duration of the intervention is one week.

Method of measurement

Braden Grading Scale

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group1: After washing the heel of the patients is prone to bed sore,Once a day, it will be dressed for a week with 4 cc of standard fish oil and at the end of the week it will be evaluated (Cooperative company producing powder and oil of Babolsar, Mazandaran province, Babolsar city).

Category

Prevention

2

Description

Intervention group 2:After washing the heel of the patients is prone to bed sore,Once a day, it will be dressed for a week with 4 cc of standard olive oil and at the end of the week it will be evaluated (Loya Iran Co., Gilan, Roodbar

Category

Prevention

3

Description

Intervention group3: After washing the heel of the

patients is prone to bed sore, Once a day, it will be dressed for a week with 5 cc of honey and at the end of the week it will be evaluated (Standard honey from Shahd Golha Co., Mashhad, Imam Reza Street, facing Mashhad Hotel) "

Category

Prevention

4**Description**

Control group: Control group receive routine cares will include the change position every 2 hours and use of wavy mattress. All intervention groups will also receive routine care.

Category

Prevention

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

Shahid Beheshti hospital in Yasuj

Full name of responsible person

Mohammad Behnammoghadam

Street address

Bagherkhan street, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591959497

Phone

+98 74 3322 5041

Email

mbehnam1363@gmail.com

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

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Ali Mosavizadeh

Street address

Shahid Motahari Blvd., Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3334 6078

Email

Health.epid@gmail.com

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

Yes

Title of funding source

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Master of Critical Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Montazeri Street, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591959497

Phone

+98 74 3322 5041

Email

mbehnammoghadam@yahoo.com

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

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Behnammoghadam

Position

Master of Critical Care Nursing

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mbehnammoghadam@yahoo.com

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Postal code
7591959497
Phone
+98 74 3322 5041
Email
mbehnammoghadam@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Mohammad Behnammoghadam
Position
Master of Critical Care Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Montazeri Street
City
Yasuj
Province

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

After conducting a clinical trial and identifying the results, We will decide to publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available