

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Study of the effect of fish oil in prevention of pressure ulcer of hospitalized patients admitted to intensive care unit.

Protocol summary

Study aim

Determination of the Effect of Fish Oil on Prevention of Pressure Wound in Patients Admitted to the Intensive Care Unit

Design

A randomized clinical trial with a control group, with three parallel groups

Settings and conduct

The present study will be carried out in Besat hospital of Hamedan in 1398. In this study 102 patients will be treated and controlled in the placebo group. In all three groups of patients, routine care, such as a change in position every three hours will be performed. Intervention group In addition to regular care, 2 cc of fish oil will be gently rubbed by the researcher daily in the sacrum area. In the placebo group, soybean oil will be used at the place of interest.. This study will be performed on each patient for five days, and the assessment will be evaluated on a daily basis by the National Pressure Ulcer Advisory Panel (NPUAP).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Stable hemodynamic status, Having a healthy skin Exclusion criteria: Dissatisfaction with the patient and their family to participate in the study, diabetes, drug addiction

Intervention groups

In this study 102 patients were randomly assigned into three groups of placebo, intervention and control. In all three groups of patients, routine care, such as a change in position every three hours and the use of mats, will be performed. Intervention group In addition to regular care, 2 cc of fish oil will be gently rubbed by the researcher daily in the sacrum area. In the placebo group, soybean oil(no therapeutic effect) will be used. In the control group, no special action will be taken.

Main outcome variables

Pressure ulcers grade 1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N23**

Registration date: **2019-04-29, 1398/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-29, 1398/02/09**

Update count: **0**

Registration date

2019-04-29, 1398/02/09

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of fish oil in prevention of pressure ulcer of hospitalized patients admitted to intensive care unit.

2019-02-26, 1397/12/07

Ethics committee reference number
IR.UMSHA.REC.1397.776

Public title

effect of fish oil in preventing pressure ulcer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Stable hemodynamic status Healthy skin Not sensitivity to seafood

Exclusion criteria:

Dissatisfaction with the patient and their family to participate in the study Diabetes Drug addiction

Age

From **18 years** old to **85 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using 6-point permutational block method and randomization was done by computer software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

Health conditions studied

1

Description of health condition studied

Skin integrity disorder

ICD-10 code

L98.9

ICD-10 code description

Disorder of the skin and subcutaneous tissue, unspecified

Primary outcomes

1

Description

pressure ulcer

Timepoint

Before and five days after intervention

Method of measurement

National pressure ulcer advisory panel checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group In addition to regular care, 2 cc of fish oil will be gently rubbed by the researcher daily in the sacrum area

Category

Prevention

2

Description

Placebo group: In the placebo group,soybean oil(without having any therapeutic effect) will be used at the skin of target area

Category

Placebo

3

Description

Control group: In the control group other than routine care, no special action will be taken.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Reza Borzou

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

borzou@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

s-bashirian@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Reza Borzou

Position

Hamadan

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

borzou@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Samira Sadeghi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

S.Samira.Sadeghi65@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mehdi Molavi

Position

Instructore

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

m.molavi@umsha.ac.ir

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