Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effectiveness of rose oil and fish oil versus placebo in preventing pressure ulcers in patients admitted to intensive care units: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of the effectiveness of rose oil and fish oil versus placebo in preventing pressure ulcers in patients admitted to intensive care units

Design

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which 66 eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Besat Hospital in Hamadan, involving 66 eligible patients admitted to intensive care units. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 75 years, Admission to the intensive care unit within the last 24 hours, Completely intact skin or, at most, blanchable erythema in the sacral region, Exclusion criteria: Stage 1 or higher pressure ulcer in the sacral region, Any severe active skin disease, Extensive burns or open wounds in the sacral or gluteal regions, Malnutrition, Diarrhea

Intervention groups

Intervention Group 1: Application of rose oil to the patient's sacral region three times daily for five days Intervention Group 2: Application of fish oil containing omega-3 fatty acids to the patient's sacral region three times daily for five days Control Group: Application of polyethylene glycol 400 to the patient's sacral region three times daily for five days

Main outcome variables

Primary outcome: Average time to pressure ulcer onset

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N620**
Registration date: **2026-09-14, 1405/06/23**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **0**

Registration date

2026-09-14, 1405/06/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of rose oil and fish oil versus placebo in preventing pressure ulcers in patients admitted to intensive care units: a double-blind randomized clinical trial

Public title
Comparison of the effectiveness of rose oil and fish oil versus placebo in preventing pressure ulcers in patients admitted to intensive care units

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 75 years Admission to the intensive care unit within the last 24 hours, Completely intact skin or, at most, blanchable erythema in the sacral region,

Exclusion criteria:
Stage 1 or higher pressure ulcer in the sacral region, Any severe active skin disease, Extensive burns or open wounds in the sacral or gluteal regions, Malnutrition, Diarrhea

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be performed using block randomization. To achieve this, six sheets of paper will be prepared - two with the name of "Intervention 1," two with the name of "Intervention 2," and two with the name of "Control." These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs will be administered in coded envelopes. Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. The person delivering the medications will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a double-blind study.

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
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2026-09-12, 1405/06/21

Ethics committee reference number
IR.UMSHA.REC.1405.467

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
Average time to pressure ulcer onset

Timepoint
During the first five days post-intervention

Method of measurement
Via clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Application of rose oil to the patient's sacral region three times daily for five days
Category
Treatment - Drugs

2

Description
Intervention Group 2: Application of fish oil containing omega-3 fatty acids to the patient's sacral region three times daily for five days
Category
Treatment - Drugs

3

Description
Control Group: Application of polyethylene glycol 400 to the patient's sacral region three times daily for five days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan
Full name of responsible person
Shadi Pordel
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
Shadi.pordel1999@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Alireza Soltanian
Street address
Hamadan University of Medical Sciences, Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@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
Shadi Pordel
Position
Nursing Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
Shadi.pordel1999@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Shokouhi

Position
Specialist in Disaster and Emergency Health

Latest degree
Ph.D.

Other areas of specialty/work
Health in Emergency and Disaster

Street address
School of Nursing and Midwifery, Hamadan University of Medical Sciences, Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
mrezashokouhi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Jalal Poorolajal

Position
Professor of Epidemiology

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
School of Public Health, Hamadan University of Medical Sciences, Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0090

Email
poorolajal@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