

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation the effect of fish oil supplementation on glucose homeostasis and inflammatory markers in patients with mild burn

Protocol summary

Study aim

The purpose of the present study is to investigate the effect of supplementing with fish oil on glucose homeostasis, inflammation (as primary outcomes) and some secondary clinical outcomes including length of stay in ICU, length of stay in hospital, incidence of infection in adults with mild burns (<20%).

Design

A controlled, parallel-group, double-blinded, randomized clinical trial on 22 patients with mild burns. The software will be used for randomization.

Settings and conduct

Patients with mild burns who are admitted to Ayatollah Mousavi Hospital in Zanjan and need enteral nutrition, the patient and the person analyzing the outcome are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

The studied population are men and women aged 18 to 65 years, with consciousness more than 9, who have mild degree of burn, less than 20% of the body surface has been burned, and have been admitted to Ayatollah Mousavi Hospital, Zanjan, and there is no underlying diseases including thyroid, cardiovascular, cancer, diabetes, kidney and liver disorders and need nutritional support through the enteral method.

Intervention groups

fish oil (as intervention group) and corn oil (as placebo)

Main outcome variables

fasting blood glucose and insulin, ESR and CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231031059911N1**

Registration date: **2023-11-29, 1402/09/08**

Registration timing: **prospective**

Last update: **2023-11-29, 1402/09/08**

Update count: **0**

Registration date

2023-11-29, 1402/09/08

Registrant information

Name

Mir Ali Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3315 6300

Email address

miralimsvi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of fish oil supplementation on glucose homeostasis and inflammatory markers in patients with mild burn

Public title

omega-3 fatty acids in burn

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mild burns or who with less than 20% of the body surface Patients with a level of consciousness higher than 9

Exclusion criteria:

Age less than 18 and more than 65 years Moderate to severe burns or involvement of less than 20% of the body surface Patients who need parenteral nutrition other diseases such as thyroid, cardiovascular, cancer, diabetes, kidney and liver disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization will be used as two groups with 5-number blocks including 2 participant in each group and the last block one patient. randomization unit is person and we will use random allocation software for this purpose. random coded boxes will be used for concealment. At this method, cans with similar weight, shape and color which are numbered according to the random sequence will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participating patients are aware of the general plan, but will be placed in one of the two intervention or placebo groups using the code. The outcome analyzer who will analyze the laboratory results is also not aware of the grouping and will provide the results to the researcher using the code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Zanzan University of Medical Sciences

Street address

Azadi Blv, Deputy of Research and Thechnology,

Zanzan University of Medical Sciences

City

Zanzan

Province

Zanzan

Postal code

4513956184

Approval date

2023-10-18, 1402/07/26

Ethics committee reference number

IR.ZUMS.REC.1402.163

Health conditions studied

1

Description of health condition studied

mild burn

ICD-10 code

T20-T32

ICD-10 code description

T20-T32

Primary outcomes

1

Description

fasting blood glucose

Timepoint

At the The beginning of the study (before the start of the intervention) and 21 days after the start of consumption

Method of measurement

Laboratory

2

Description

fasting insulin

Timepoint

At the The beginning of the study (before the start of the intervention) and 21 days after the start of consumption

Method of measurement

ELISA kit

3

Description

C-reactive protein

Timepoint

At the The beginning of the study (before the start of the intervention) and 21 days after the start of consumption

Method of measurement

ELISA kit

4

Description

Erythrocyte sedimentation rate

Timepoint

At the The beginning of the study (before the start of the intervention) and 21 days after the start of consumption

Method of measurement

Laboratory

miralimsvi@gmail.com

Secondary outcomes**1****Description**

length of hospital stay

Timepoint

from hospital admission to discharge

Method of measurement

counting the days

2**Description**

length of intensive care unit stay

Timepoint

From the beginning of hospitalization to discharge from the intensive care unit

Method of measurement

counting the days

Intervention groups**1****Description**

Intervention group: Fish oil (Karen Company, Iran) at a dose of 3 gram per day through gavage for 3 weeks

Category

Prevention

2**Description**

Control group: Corn oil at a dose of 3 gram per day through gavage for 3 weeks

Category

Placebo

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

Ayatollah Mousavi Hospital

Full name of responsible person

Mir Ali Mousavi

Street address

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Samad Nadri

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Research@zums.ac.ir

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

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Neda Mousavi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be provided anonymously and upon request by the corresponding author of the article.

When the data will become available and for how long

after paper publication

To whom data/document is available

Vice Chancellor of University Research and Technology

Under which criteria data/document could be used

Vice Chancellor of University Research and Technology

From where data/document is obtainable

Vice Chancellor of University Research and Technology

What processes are involved for a request to access data/document

sending request to the Vice Chancellor of University

Research and Technology

Comments