

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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 Zanjan University of Medical Sciences

**Street address**

Azadi Blv, Deputy of Research and Thechnology,

Zanjan University of Medical Sciences

**City**

Zanjan

**Province**

Zanjan

**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**

بلوار دکتر یوسف ثبوتی

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3315 6000

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Samad Nadri

**Street address**

Azadi Blv

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4513956184

**Phone**

+98 24 3342 0460

**Email**

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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Honarestan St., Janbazan St., Shahide avval Ave

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neda.mousavi@zums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Seyedeh Neda Mousavi

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**Person responsible for updating data**

**Contact**

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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**