

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the adjunctive use of omega3 fatty acids in periodontal parameters

#### Protocol summary

##### Study aim

Determining the effect of omega-3 supplement on the recovery of patients with periodontitis

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 44 patients.

##### Settings and conduct

Patients with chronic periodontitis referred to the periodontology department of the School of Dentistry of Shahid Sadoughi University of Medical Sciences, Yazd, after examination and inclusion criteria, are examined and randomly divided into two groups of intervention and control. In addition to the usual non-surgical treatment of periodontitis (scaling and root planning with ultrasonic devices), daily consumption of one omega-3 soft gel for 3 months in case group and daily use of a soft gel containing placebo for 3 months in control group. The drug consultant will distribute the drug to the groups and the patient and the researcher are not aware of any of the drugs received (placebo or omega 3).

##### Participants/Inclusion and exclusion criteria

Patients with severe periodontitis who do not have systemic disease or conditions that interfere with periodontal status.

##### Intervention groups

Intervention group: In addition to the usual non-surgical treatment of periodontitis (scaling and root planning with ultrasonic devices), daily consumption of one omega-3 soft gel for 3 months  
Control group: In addition to the usual non-surgical treatment of periodontitis (scaling and root planning with ultrasonic devices), daily use of a soft gel containing placebo for 3 months

##### Main outcome variables

periodontal pocket depth, clinical attachment loss, bleeding index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151013024509N5**  
Registration date: **2021-07-17, 1400/04/26**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-17, 1400/04/26**

Update count: **0**

##### Registration date

2021-07-17, 1400/04/26

##### Registrant information

##### Name

Fahimeh Rashidi Maybodi

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 519 6227

##### Email address

f-rashidi63@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the adjunctive use of omega3 fatty acids in periodontal parameters

**Public title**

Evaluation of the adjunctive use of omega3 fatty acids in gingival diseases

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The age should be between 30-60 years clinical attachment loss should be greater than 3 mm. The patient should be healthy.

**Exclusion criteria:**

smoking history of periodontal treatment in last 6 months presence any disease or systemic conditions that have interfered with wound healing. inflammatory conditions in the oral cavity use the medicines affect periodontium .

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into control and intervention groups using simple random allocation method and random number table. the total sample size is 44 people who were randomly divided into two groups of 22 people and a random table was provided to the researcher and based on it. The control and intervention group is determined. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process and will not have the authority to change or predict the status of individuals.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Medications are coded by the consulting pharmacist and the examiner and patient will not know the type.omega3 soft gel and its placebo is completely similar.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

•Ethics committee of shahid sadooghi Yazd University of Medical Sciences

**Street address**

imam reza bulvar,School of Dentistry, University of Medical Sciences, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

894815667

**Approval date**

2021-05-10, 1400/02/20

**Ethics committee reference number**

IR.SSU.REC.1400.025

**Health conditions studied****1****Description of health condition studied**

periodontitis

**ICD-10 code**

K05.32

**ICD-10 code description**

Chronic periodontitis, generalized

**Primary outcomes****1****Description**

chronic periodontitis

**Timepoint**

initial examination-1 and 3 months after using omega3

**Method of measurement**

evaluation of clinical periodotal parameters

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

periodontal pocket depth

**Timepoint**

initial examination, 1and 3 months after consumption OMEGA3

**Method of measurement**

measurement by periodontal probe

**2****Description**

clinical attachment loss

**Timepoint**

initial examination, 1and 3 months after consumption OMEGA3

**Method of measurement**

measurement by periodontalprobe

### 3

#### **Description**

bleeding index

#### **Timepoint**

initial examination, 1and 3 months after consumption  
OMEGA3

#### **Method of measurement**

Percentage of bleeding areas(6 areas around the tooth)

## **Intervention groups**

### 1

#### **Description**

Intervention group: After the usual non-surgical treatment of chronic periodontitis (scaling akd root planing , the intervention group will take the 1000mg omega 3 soft gel supplement, manufactured by Yas Daroo Meybod Company for 3 months. The variables will be checked again after 1 and 3 months.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: After the usual non-surgical treatment of chronic periodontitis (scaling akd root planing with ultrasonic devices) , this group will take placebo soft gel, manufactured by Yas Daroo Meybod Company for 3 months. The variables will be checked again after 1 and 3 months.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

periodontology department , yazd dental school

##### **Full name of responsible person**

Mahsa Fakhari

##### **Street address**

Imam Reza Boulevard,Yazd dental school

##### **City**

Yazd

##### **Province**

Yazd

##### **Postal code**

8914815667

##### **Phone**

+98 35 3625 5880

##### **Email**

m.fakhari2012@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Hassan Mozaffari

##### **Street address**

Shahid bahonar square

##### **City**

yazd

##### **Province**

Yazd

##### **Postal code**

8916844933

##### **Phone**

+98 35 1725 8413

##### **Email**

mozaffari@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Mahsa Fakhari

##### **Position**

post graduate student

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Dentistry

##### **Street address**

Imam Reza Boulevard,yazd dental school

##### **City**

yazd

##### **Province**

Yazd

##### **Postal code**

8914815667

##### **Phone**

+98 35 3625 5880

**Email**

m.fakhari2012@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mahsa Fakhari

**Position**

post graduate student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Imam Reza Boulevard, yazd dental school

**City**

yazd

**Province**

Yazd

**Postal code**

8914815667

**Phone**

+98 35 3625 5880

**Email**

m.fakhari2012@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Farhad Fatehi

**Position**

Responsible for International Relations

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

ImamReza boulevard,yazd dental school

**City**

yazd

**Province**

Yazd

**Postal code**

8914815667

**Phone**

+98 35 3625 5880

**Email**

ffatehi@gmail.com

## 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