

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)

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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

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

City

yazd

Province

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hassan Mozaffari

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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

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Person responsible for scientific inquiries

Contact

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Position

post graduate student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Farhad Fatehi

Position

Responsible for International Relations

Latest degree

Specialist

Other areas of specialty/work

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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