

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Efficacy of oral supplement omega-3 in treatment of recurrent aphthous stomatitis and improvement of oral health related quality of life

Protocol summary

Study aim

Evaluation the efficacy of oral supplement omega-3 in treatment of recurrent aphthous stomatitis and improvement of oral health related quality of life

Design

In this double-blind clinical trial, 40 patients with recurrent aphthous stomatitis who referred to the Oral Medicine Department of the Faculty of Dentistry of Babol University of Medical Sciences were selected. After matching with the inclusion and exclusion criteria, these individuals are randomly (flip the coin) assigned to two groups of 20 control and intervention groups. The placebo group receives placebo capsules and the intervention group receives omega-3 capsules (DeraPakhsh, Iran).

Settings and conduct

The participants were selected from patients referred to the clinic of oral medicine department of the faculty of dentistry of Babol university of medical sciences. Participants who met the inclusion/exclusion criteria received verbal information about the study. Intervention group received omega-3 capsules of 1000 mg each (Zahravi Company, Tehran, Iran) tree times a day for six month and control group received placebo capsules with the same prescription. At baseline appointment and monthly follow-up visits (for 6 months), a questionnaire for the average number of ulcers, the amount of pain (VAS), and the amount of time of the wound present are filled for each patient. patients filled persian version of the chronic oral mucosal disease questionnaie (COMDQ) were ranked by the patients To evaluate treatment effectiveness two times: at the baseline appointment and 6 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria in case and control groups: both male and female with older than 18 years of age; having recurrent minor aphthous ulcer for at least 1 year ; presenting with 1 to 3 aphthous ulcers (of less than 48 hours' duration) exclusion criteria in case and control

groups: individuals heart, liver, or kidneys disease; pregnancy or lactation; ulcers as a manifestation of systemic disorders such as ulcerative colitis, Crohn disease, Behçet syndrome ; use of medications such as systemic steroids, immunomodulatory agents, or nonsteroidal anti-inflammatory drugs within 1 month before study entry.

Intervention groups

experimental group (omega-3 group) included patients with recurrent aphthous stomatitis who received omega-3 soft gelatin capsules (Zahravi Company, Tehran, Iran) of 1000 mg 3 times daily control group (placebo group) included patients with recurrent aphthous stomatitis who received placebo soft gelatin capsules 3 times daily

Main outcome variables

number of new ulcer outbreaks; the average level of pain using a visual analog scale (VAS); the average duration of ulcer episodes; the average score of COMDQ

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160112025986N3**

Registration date: **2018-01-07, 1396/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-07, 1396/10/17**

Update count: **1**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2017-12-22, 1396/10/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral supplement omega-3 in treatment of recurrent aphthous stomatitis and improvement of oral health related quality of life

Public title

Efficacy of oral supplement omega-3 in treatment of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

both male and female with older than 18 years of age having recurrent minor aphthous ulcer for at least 1 year with a frequency of at least 1 outbreak per month presenting with 1 to 3 aphthous ulcers (of less than 48 hours' duration) with a size no greater than 10 mm in diameter without anesthesia or paresthesia

Exclusion criteria:

individuals who had concurrent clinical conditions that could pose a health risk to the participants, including serious heart, liver, or kidney dysfunctions pregnancy or lactation ulcers as a manifestation of systemic disorders such as ulcerative colitis, Crohn disease, Behçet syndrome, or serious anemia use of medications such as systemic steroids, immunomodulatory agents, antibiotics, or nonsteroidal anti-inflammatory drugs within 1 month before study entry

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals were randomly divided into two groups of omega-3 capsules and placebo capsules using coin throwing.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the error from the knowledge of the patient or assessor's dentist to the type of treatment received and its possible impact on the outcome of the study, a double-blind study is done. Given that the omega-3 capsules and placebo are placed in the same full capsule, the patient and the assessing dentist are not aware of the type of medication received.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University of Medical Sciences

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Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran

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۴۷۱۷۶-۴۷۷۴۵

Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

MUBABOL.REC.1396.67

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

Recurrent Aphthous Stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Number of aphthous ulcer

Timepoint

First appointment; monthly for 6 months

Method of measurement

Count the ulcers

2

Description

Level of pain

Timepoint

First appointment, monthly for 6 months

Method of measurement

Visual Analogue Scale (VAS)

3

Description

average duration of ulcer episodes

Timepoint

First appointment; monthly for 6 months

Method of measurement

Number of days

4

Description

The average score of COMDQ

Timepoint

First appointment; 6 month later

Method of measurement

Filling the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: omega-3 soft gelatin capsules(Zahravi Company, Tehran, Iran) of 1000 mg 3 times daily , 6 months

Category

Treatment - Drugs

2

Description

Control group: placebo soft gelatin capsules 3 times daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry

Full name of responsible person

Atena Shirzad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Atena Shirzad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable