Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Eevaluation 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 than18 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 aphtous 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 outbreaksک 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

Atena Ahirzad

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 than18 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 than10 mm in diameter withoutanesthesia or paresthesia
Exclusion criteria:
individuals who had concurrent clinical conditions that could pose a health risk to the participants,including serious heart, liver, or kidneydys functions pregnancy or lactation ulcers as a manifestationof systemic disorders such as ulcerative colitis, Crohn disease, Behçet syndrome, or serious anemia use of medications such as systemic steroids,immunomodulatory agents, antibiotics, or nonsteroidalanti-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
Street address
Babol University of Medical Science, Ganj Afrooz Avenue, Babol, Mazandaran, Iran
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Mazandaran
Postal code
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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 Aphtous Stomatitis
ICD-10 code
K12.0
ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
Number of aphtous 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