Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy of Omega 3 in the treatment of recurrent aphthous stomatitis: A randomized parallel controlled trial

Protocol summary

Summary

Recurrent aphthous stomatitis (RAS) is a condition which is marked by painful ulcers that develop on non-keratinized oral mucosa. Omega 3 contains anti inflammatory and analgesic effects. clinical study with double control and placement of patients in the two groups will perform. Of the groups of patients referred to the Department of Oral Medicine, School of Dentistry, Zahedan selected. patients using randomly divided into A and B groups. For patients in group A 1000 mg of omega 3 capsules (made in Iran, drug distribution company) three times daily for 6 months, patients in group B placebo capsules (made of Iran, drug distribution company) three times in the same day Omega 3 and 6 months is recommended. The questionnaire for each patient, including age, sex, occupation, medical history, status and the number and size of wounds, disease duration, recurrence intervals, the pain of ulcers, previous treatments performed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041620377N2**
Registration date: **2015-05-26, 1394/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-26, 1394/03/05

Registrant information

Name

Tahereh Nosratzehi

Name of organization / entity

Dental School of Zahedan University

Country

Iran (Islamic Republic of)

Phone

+98 915 348 0151

Email address

nosratzehi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2015-04-15, 1394/01/26

Expected recruitment end date

2016-04-14, 1395/01/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Omega 3 in the treatment of recurrent aphthous stomatitis: A randomized parallel controlled trial

Public title

The efficacy of Omega 3 in the treatment of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: More than four days since the beginning aphthous ulcers they not passed; Before go for treatment of aphthous lesions are not using; Patients must agree to cooperate with the project (Moral satisfaction). Exclusion criteria: Another solution is to use the drug for the treatment of pests; Not recommended to use the drug according to patient; Not referring a patient for re- examination; Pregnant women; systemic disease

and drug use

Age
From **13 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: Stratified Blocking

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Oral medicine department, faculty of dentistry, Azadegan street,Zahedan

City
Zahedan

Postal code
9811111111

Approval date
2015-04-14, 1394/01/25

Ethics committee reference number
1438

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
Ulser Size

Timepoint
On days 0، 2، 4، 6، 10، 14

Method of measurement
Caliper

2

Description
Number of Ulcer

Timepoint
On days 0، 2، 4، 6، 10 ،14

Method of measurement
counts Of Ulcers

Secondary outcomes

1

Description
level of pain

Timepoint
On days 0، 2، 4، 6، 10، 14

Method of measurement
Visual Analogue Scale

2

Description
level of Burning

Timepoint
On days 0، 2، 4، 6، 10، 14

Method of measurement
Visual Analogue Scale

3

Description
Recurrence of Lesion

Timepoint
The first week, second week, first month of the third, fourth month, Fifth Month, Sixth Month

Method of measurement
Clinical Examination

Intervention groups

1

Description
Intervention group: 1000 mg capsule omega 3 (made of Iran, drug distribution company) three times per days for 6 months

Category
Prevention

2

Description
Control group: 1000 mg capsule placebo (made of Iran,

drug distribution company) three times per days for 6 months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University Of Medical Sciences

Full name of responsible person

Dr Tahereh Nosratzehi

Street address

Oral medicine department, faculty of dentistry, Azadegan street, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Tahereh Nostatzehi

Street address

Oral medicine department, faculty of dentistry, Azadegan street, Zahedan

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Tahereh Nostatzehi

Position

Assistant Professer Zahedan University of Medical Sicences

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty