

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 Nosratzahi

##### Name of organization / entity

Dental School of Zahedan University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 348 0151

##### Email address

nosratzahi@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 Aphthous 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 Professor Zahedan University of Medical

Sicences

**Other areas of specialty/work**

**Street address**

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**Full name of responsible person**

Dr Tahereh Nosratzehi

**Position**

Assistant Professor of Zahedan University of Medical  
Sicences

**Other areas of specialty/work**

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**Full name of responsible person**

Dr Tahereh nosratzehi

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Assistant Professor of Zahedan University of Medical  
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**Email**

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**Web page address****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*