

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the effectiveness of Zinc Sulfate mucoadhesive tablet in the improvement of Recurrent Aphthous Stomatitis (RAS)

Protocol summary

Study aim

Evaluation of the effectiveness of Zinc Sulfate mucoadhesive tablet in the improvement of Recurrent Aphthous Stomatitis (RAS)

Design

The randomized clinical trial with the intervention and control group, parallel groups, double blinded

Settings and conduct

This study is a double; blinded clinical trial which was performed at Sari, Faculty of Dentistry Clinic.

Participants/Inclusion and exclusion criteria

Including criteria: Individuals with adequate knowledge and literacy, age group 16 to 45 years old, Aphthous diagnostic criteria and ability to fill out the consent form legally. Excluding criteria: Individuals with major recurrent aphthous stomatitis and herpetic form, aphthous ulcers other than labial and buccal sites, systemic disease, consuming immunosuppressive drug, using denture, consuming antibiotics, pregnancy, poor oral hygiene, unable to receive Zinc sulfate mucoadhesive tablet, in syndromes which Aphthous ulcers are one of the manifestations, like Behcet's syndrome, Individuals who are prescribed a non-Zinc drug for Aphthous improvement, Smoking.

Intervention groups

In the intervention group, the mucoadhesive tablet was given 3 times a day (morning, noon, and night). In the control group, the same was done with a placebo.

Main outcome variables

Eritmathous halo; improvement period; pain

General information

Reason for update

Acronym

RAS

IRCT registration information

IRCT registration number: **IRCT20151109024975N9**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Gohar Eslami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2018-01-28, 1396/11/08

Actual recruitment end date

2018-05-26, 1397/03/05

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Zinc Sulfate mucoadhesive tablet in the improvement of Recurrent Aphthous Stomatitis (RAS)

Public title

Effect of Zinc in improvement of Aphthous

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with adequate knowledge and literacy Age group is 16 to 45 years old Aphthous diagnostic criteria Ability to fill out the consent form legally

Exclusion criteria:

Individuals with major recurrent aphthous stomatitis & herpetic form Patients who had aphthous lesions in other areas than Labial & Buccal mucosa Patients with systemic disease during last month Patients with Denture Patients consuming antibiotics Patients with pregnancy Individuals with poor oral hygiene Individuals who are not capable of receiving Zinc sulfate mucoadhesive Individuals who have syndromes which Aphthous ulcers are one the manifestations, like Behcet's syndrome Individuals who are prescribed a non-Zinc drug for Aphthous improvement Smoking Individuals who consume Immunosuppressive drug during last month Individuals who couldn't resume the study according to social or personal issues

Age

From **16 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The examiner is unaware of the contents of the boxes of drugs and they are quite similar.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vali;Asr highway

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2018-04-24, 1397/02/04

Ethics committee reference number

IR.MAZUMS.REC.1397.004

Health conditions studied

1

Description of health condition studied

Recurrent Aphthous Stomatoitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Diameter of eritmathous halo

Timepoint

Zero (before entering the study); third; fifth and seventh days

Method of measurement

Metal caliber

Secondary outcomes

1

Description

Period of improvement

Timepoint

Zero (before entering the study); third; fifth and seventh days

Method of measurement

Visual Analogue Scale Questionnaire

Intervention groups

1

Description

Intervention group: Patients received mucoadhesive tablets three times a day containing Zinc Sulfate (morning, afternoon and night). How to use the mucoadhesive tablets was taught to patients so that they should avoid eating and drinking for 30 minutes after applying the tablet. The chemical composition of the Zinc Sulfate mucoadhesive tablets tablet: A certain amount of Zinc Sulfate 8H2O (containing 5 mg of Zinc)

was selected as a therapeutic dose to evaluate the effects of this substance on the improvement of oral Aphthous. Other components include Carbopol 940 and Sodium Alginate as a tablet binding agent to the mucus, starch as a filler to the body of the tablet, and sucrose to create the proper taste and help the pill to open gradually in the mouth.

Category

Treatment - Drugs

2**Description**

Control group: Patients received mucoadhesive tablets three times a day containing Placebo (morning, afternoon and night). How to use the mucoadhesive tablets was taught to patients so that they should avoid eating and drinking for 30 minutes after applying the tablet.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sari Faculty of Dentistry clinic

Full name of responsible person

Anahita Ghorbani

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Khazar boulevard

City

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Mazandaran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Mazandaran

Postal code

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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

Sari University of Medical Sciences

Proportion provided by this source

90

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**

Mazandaran University of Medical Sciences

Full name of responsible person

Anahita Ghorbani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Vali;Asr highway

City

Sari

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Postal code

۴۸۱۵۷۳۳۹۷۱

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Mazandaran University of Medical Sciences

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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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

Not applicable

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Sharing the information on the main consequence is possible.

When the data will become available and for how long

Beginning the access period is 12 months after printing the results.

To whom data/document is available

Only available to scholars working in academia and scientific institutes.

Under which criteria data/document could be used

It is allowed any kind of analysis, after receiving the results.

From where data/document is obtainable

Dr. Anahita Ghorbani; Oral & Maxillofacial Diagnostic section; Sari Dentistry Faculty; Khazar Blvd; Khazar Sq; Sari

What processes are involved for a request to access data/document

First, send an email to the response officer. The applicant will be contacted after the necessary investigations.

Comments