

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effectiveness of N-acetylcysteine mucosa adhesive in comparison with placebo on recurrent aphthous stomatitis (RAS) in the specific age group 16-45 years old

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of N-acetylcysteine mucosa adhesive in comparison with placebo on recurrent aphthous stomatitis (RAS)

##### Design

The nonrandomized 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

Entry criteria: Age group 16-45, and aphthous diagnostic criteria and legally able to fill out their the consent form.  
Excluding criteria: Individuals with major recurrent aphthous stomatitis and herpetic form, people with systemic diseases, denture users, people taking immunosuppressive drugs, antibiotic recipients, people with low levels of health, pregnant patients, people who use other drugs to treat aphthous ulcer, in syndromes which Aphthous ulcers are one of the manifestations, like Behcet's syndrome, smokers.

##### 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: **IRCT20180728040614N1**

Registration date: **2018-09-29, 1397/07/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

##### Registration date

2018-09-29, 1397/07/07

##### Registrant information

###### Name

Anahita Ghorbani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3330 0300

###### Email address

a.ghorbani1@mazums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-11-06, 1397/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effectiveness of N-acetylcysteine mucosa adhesive in comparison with placebo on recurrent aphthous stomatitis (RAS) in the specific age group 16-45 years old

##### Public title

Effect of N-acetylcysteine in the improvement of Aphthous

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age group 16 to 45 years old Diagnostic criteria for aphthous stomatitis sufficient knowledge to understand the description provided for treatment Legally the patients are able to complete their consent form

### Exclusion criteria:

People who take suppressive drugs during the past month People with Systemic Disease People with syndromes such as Behcet's syndrome, which aphthous ulcer is one of the manifestations . Patients who develop aphthous ulcers in areas other than labial and buccal mucosa People with recurrent stomatitis Herpes form People with recurrent major aphthous stomatitis Patients with poor oral hygiene Pregnant women Antibiotic users Patients with dentures People who use other drugs to treat aphthous ulcer and in general people who cant stay or cant continue cooperation till end of research due to personal and social reasons Smoking Individuals

## 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**

## 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 and the boxes of medications are quite similar.

## Placebo

Used

## Assignment

Parallel

## Other design features

The present study is a double-blinded clinical trial study. The examiner is unaware of the contents of the boxes and the boxes of medications are quite similar. Patients present in the study will be divided into two groups. In the first group, patients will receive 3 times daily mucosa adhesive tablets, so that they will use morning, afternoon and night. How to use a mucous adhesive tablet is taught to patients, which drinking and eating should be avoided for 30 minutes when mucosa adhesive tablet applied to the area with an aphthous ulcer. In the control group, the same is done with placebo.

## 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

2018-08-25, 1397/06/03

#### Ethics committee reference number

IR.MAZUMS.REC.1397.2955

## 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

Diameter of eritmathous halo

#### Timepoint

Days zero (before entering the study); third; fifth and seventh

#### Method of measurement

Metal caliber

### 2

#### Description

Period of improvement

#### Timepoint

Days zero (before entering the study); third; fifth and seventh

#### Method of measurement

Visual Analogue Scale Questionnaire

## Secondary outcomes

### 1

#### Description

The amount of pain

#### Timepoint

Days zero (before entering the study); third; fifth and seventh

#### **Method of measurement**

Visual Analogue Scale Questionnaire

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Patients received mucoadhesive tablets three times a day containing N-acetylcysteine (morning, afternoon and night). How to use a mucoadhesive tablet was taught to the patients, which drinking and eating must be avoided for 30 minutes after application. The chemical composition of the mucoadhesive tablet: 25 mg of NAC was selected as the appropriate treatment dose to evaluate the effects of this substance on the accelerated improvement of mouth ulcer. Other components of the tablet include Carbopol 940 and sodium alginate as a binding agent to the oral mucosa, starch to adjust the weight of the tablet, also to adjust the disintegrant time, and sucrose to make the taste. The components of the formulation were passed through a mesh of 80 (No. 80) and mixed together. Then they were pressed with a single-pill tablet press.

##### **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 the 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

###### **Street address**

Khazar boulevard

###### **City**

Sari

###### **Province**

Mazandaran

###### **Postal code**

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###### **Phone**

+98 11 3340 5474

###### **Email**

anahita1802@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Mazandaran University of Medical Sciences

###### **Full name of responsible person**

Dr. Majid Saeedi

###### **Street address**

Vali;Asr highway

###### **City**

Sari

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+98 11 4001 3304

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anahita1802@yahoo.com

##### **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

###### **Province**

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## Person responsible for scientific inquiries

**Contact**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Assistant professor

**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**

Start of the access period 12 months after publishing the results

**To whom data/document is available**

Only available to scholars working in academic and scientific institutes.

**Under which criteria data/document could be used**

After receiving the results. any kind of analysis is allowed.

**From where data/document is obtainable**

Dr. Anahia Ghorbani; Faculty of Dentistry; Oral Diagnostic section ; 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**