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

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Iran (Islamic Republic of)

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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

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Khazar boulevard

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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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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

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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

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