

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluate the effectiveness of c-Phycocyanin mucoadhesive paste on recurrent aphthous stomatitis (RAS)

Protocol summary

Study aim

Evaluate the effectiveness of c-Phycocyanin mucoadhesive paste on recurrent aphthous stomatitis (RAS)

Design

This study is a double-blind randomized clinical trial. Using random allocation software 2, patients are distributed into two control and intervention groups (each group includes 20 people) using the randomized block method of 2.

Settings and conduct

In this study, 40 patients referred to the diagnosis department of Sari Dental Faculty, who were diagnosed with recurrent aphthous stomatitis, were divided into two control and intervention groups (each group included 20 people). The test group received the pure compound c-Phycocyanin and the control group received placebo. Patients are asked to use the paste three times a day (morning, noon and night) for 30 minutes and then not to wash their mouth or eat for half an hour. They should do this for seven days continuously. At the beginning of the study and after 3, 5, and 7 days, the diameter of the lesions and the surrounding inflammatory area are recorded with the help of a metal caliper. Patients are also taught to rate the pain intensity based on the VAS scale from zero to ten.

Participants/Inclusion and exclusion criteria

Patients must have diagnostic criteria for aphthous disease and have sufficient knowledge to understand the explanations provided for the treatment and be legally able to complete their consent form. Exclusion criteria include people taking antibiotics and immunosuppressive drugs and people who cannot continue to cooperate until the end of the study due to personal or social reasons.

Intervention groups

The intervention group received c-Phycocyanin mucosal adhesive and the control group received placebo.

Main outcome variables

Mucoadhesive c-Phycocyanin Erythematous aura Length

of recovery period the pain Age sex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240802062616N1**

Registration date: **2024-09-19, 1403/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2024-09-19, 1403/06/29**

Update count: **0**

Registration date

2024-09-19, 1403/06/29

Registrant information

Name

fatemeh taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3588 2744

Email address

fatemehtaherii7798@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-17, 1403/06/27

Expected recruitment end date

2024-11-17, 1403/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effectiveness of c-Phycocyanin mucoadhesive paste on recurrent aphthous stomatitis (RAS)

Public title

Investigating the effect of c-Phycocyanin pure compound on mouth sores

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with minor recurrent stomatitis, patients with aphthous lesions on the lips and buccal mucosa, not suffering from systemic disease, not taking immunosuppressive drugs in the past month, not using dentures, not taking antibiotics.

Exclusion criteria:

Exclusion criteria include people taking immunosuppressive drugs in the past month, people with systemic disease, people with syndromes such as Behcet's syndrome, where aphthous ulcers are one of its manifestations, patients with aphthous lesions in areas other than the lips and buccal mucosa, People with recurrent herpetiform stomatitis, People with major recurrent stomatitis, Patients with poor hygiene level, Pregnant women, Antibiotic users, Patients with dentures, People who use other drugs to treat plague and in general people who due to personal reasons or Social workers cannot continue to cooperate until the completion of the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are distributed into two control and intervention groups with the help of random allocation software 2 and with the randomized block method of 2. Blocks will be considered as quadruplets (two people will be placed in each group in each block).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are distributed into two control and intervention groups using a randomized block method of 2 (each group includes 20 people). Code A of the intervention group received mucoadhesive containing phycocyanin and code B of the placebo control group received mucoadhesive without active ingredient. The conditions

of the study are explained to the patients, but they do not know which medicine has the active ingredient.

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

Moalem Square, Building No. 2 of the University, Research Vice Chancellor

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2024-07-08, 1403/04/18

Ethics committee reference number

IR.MAZUMS.REC.1403.187

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

The amount of pain and recovery of recurrent aphthous lesions

Timepoint

Days 0 (start of study), 3, 5 and 7

Method of measurement

Determining the diameter of lesions using a metal caliper and measuring the intensity of pain using a visual analog scale (VAS).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive mucus glue three times a day (morning, noon and night).

Category

Treatment - Drugs

2

Description

Control group: receives a placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba Dental Clinic

Full name of responsible person

Dr. Anahita Ghorbani

Street address

Khazar Boulevard, Tuba Dental Clinic

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3325 4135

Email

aghorbani@mazums.ac.ir

Web page address

<https://www.mazums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

Street address

Moalem Square, Research and Technology Deputy Building

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

pajhooheshi@mazums.ac.ir

Web page address

<https://www.mazums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

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

Dr. Anahita Ghorbani

Position

Specialized doctorate in oral and dental diseases

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Khazar Boulevard, Tuba Dental Clinic

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 11 3324 4894

Email

aghorbani@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Anahita Ghorbani

Position

Specialist in oral and dental diseases

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tuba Clinic, Khazar Street, Sari

City

Sari

Province

Mazandaran

Postal code

33971-48157

Phone

+98 911 151 3085

Email

anahita1802@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Taheri

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Khazar Boulevard, Tubi Dental Clinic

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

+98 905 572 3506

Email

fatehmehtaherii7798@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

After the completion of the results plan, it will be delivered in the form of a final report and electronically (on a CD) to the Research Vice-Chancellor and Faculty of Dentistry of Mazandaran University of Medical Sciences.

When the data will become available and for how long

The decision regarding the access to the data will be the responsibility of the vice president of research and the Faculty of Dentistry of Mazandaran Faculty of Medical Sciences, as well as the supervisor.

To whom data/document is available

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

Under which criteria data/document could be used

To present the final report and write the article

From where data/document is obtainable

Vice President of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

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

A written request to the vice president of research or the Faculty of Dentistry of Mazandaran University of Medical Sciences, as well as the supervisor

Comments