# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

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+98 17 3588 2744

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**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
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Mazandaran
**Postal code**
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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
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**Web page address**
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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**
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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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Mazandaran University of Medical Sciences
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Fatemeh Taheri
**Position**
Dental student
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A Level or less
**Other areas of specialty/work**
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## 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**