# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Evaluation of the effectiveness of mallow extract mucous adhesive on recurrent aphthous stomatitis

## Protocol summary

**Study aim**
Determining the effectiveness of mallow extract mucous adhesive in treatment of recurrent aphthous stomatitis

**Design**
Control group: Placebo. Intervention group: Mallow extract mucous adhesive. Randomized double blind clinical trial. 21 patients in each group.

**Settings and conduct**
The patients in the study will be divided into two groups. In the first group, the patients will be given 3 pieces of mucus glue daily so that they use it in the morning, noon and night. Patients are taught how to use the adhesive mucus so that they should avoid eating and drinking for 30 minutes after using it. In the control group, the same operation will be done with a placebo. In order to evaluate the level of pain and healing of the lesions, the patients are clinically examined on days zero (before entering the study) 3/5/7 using a metal caliper to determine the diameter of the lesions and the inflammatory area around them. The patients are also taught It is given to determine the intensity of pain based on the VAS criterion.

**Participants/Inclusion and 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: pregnant patients, people who are not able to use mucous adhesive, people with syndromes whose manifestations are aphthous ulcers (Behcet's syndrome) , smokers, people with autoimmune diseases of the skin, mucosa , patients with Liver failure, myopathy and muscle problems, patients suffering from allergies and urticaria, and people who cannot continue the study due to personal and social reasons.

**Intervention groups**
Control group: Placebo. Intervention group: Mallow extract mucous adhesive.

**Main outcome variables**
Pain and diameter of the lesion

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170430033722N5**
Registration date: **2023-08-09, 1402/05/18**
Registration timing: **retrospective**

Last update: **2023-08-09, 1402/05/18**
Update count: **0**

**Registration date**
2023-08-09, 1402/05/18

**Registrant information**

**Name**
Tahereh Molania

**Name of organization / entity**
Mazandaran University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 11 3354 3861

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-04-05, 1402/01/16

**Expected recruitment end date**
2023-06-06, 1402/03/16

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness of mallow extract mucous adhesive on recurrent aphthous stomatitis

**Public title**

Evaluation of the effect of mallow on oral aphthous

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with minor recurrent stomatitis Patients who have aphthous lesions in the lips and buccal mucosa Absence of systemic disease Not taking immunosuppressive drugs in the last 1 month Not using dentures No use of antibiotics

**Exclusion criteria:**

**Age**

From **20 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples will be randomly assigned to two groups. Blocks will be considered as quadruplets (two subjects will be placed in each group in each block).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

randomized double blind clinical trial The patient and the evaluator do not know the type of study group

**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**

Moallem square, Deputy of Research and Technology building

**City**

Sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Approval date**

2017-06-13, 1396/03/23

**Ethics committee reference number**

IR.MAZUMS.REC.1396.2863

## 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 level of pain and healing of recurrent aphthous lesions

**Timepoint**

Days of 0 (beginning of the 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**

Control group: receives a placebo

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: 3 pieces of adhesive mucus containing mallow extract with a concentration of 10% will be given daily

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Touba dental clinic
**Full name of responsible person**
Tahereh Molania
**Street address**
Khazar Blvd, Touba dental clinic
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Pedram Ebrahim Nejad
**Street address**
MoalLem Square, Research and Technology Deputy Building
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**Fax**
**Email**
pajhooheshi@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**
Tahereh Molania
**Position**
Associate professor
**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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**Full name of responsible person**

Tahereh Molania

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**Email**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Apart from the identity data of the study participants, other information will be provided to the applicant upon request from the corresponding author of the article.

**When the data will become available and for how long**

6 months after the publication of the results

**To whom data/document is available**

everyone

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

The applicant can email the corresponding author of the article and request for information.

**From where data/document is obtainable**

Corresponding author of the article

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

The applicant can email the corresponding author of the article and request for information.

**Comments**