Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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)

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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
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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
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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
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Tahereh Molania
Position
Associate professor
Latest degree
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Other areas of specialty/work
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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