

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessment of Cinnamaldehyde mucoadhesive effect on minor recurrent aphthous stomatitis

Protocol summary

Study aim

Determination of Cinnamaldehyde mucoadhesive effect on minor recurrent aphthous stomatitis

Design

Patients present in the study will be randomly divided into two groups. In the first group, patients will receive 3 mucoadhesive every day, so that they will use morning, afternoon and night. How to use mucous membranes is taught to patients so that they should avoid drinking and drinking for 30 minutes. In the control group, the same is done with a placebo.

Settings and conduct

This is a randomized double blind clinical trial study. The study population is selected from patients referring to oral and maxillofacial diseases faculty of dental school of Mazandaran University of Medical Sciences in 1397.

Participants/Inclusion and exclusion criteria

The criteria for entering this study were those with recurrent minor stomatitis / patients with buccal mucosal lesions / no systemic disease, no use of suppressive drugs during the past month / no denture / no antibiotic use is. Also, pregnant patients / those unable to use mucous membranes / people with syndromes that are one of the symptoms of aphthous stroke (Behcet's Syndrome), smokers and those who can not continue studying for personal or social reasons up to the end , Are excluded.

Intervention groups

Patients with recurrent aphthous stomatitis, aged 20 to 40 years old, all have a history of minor ulcerations in areas such as lips and buccal mucosa.

Main outcome variables

Determination of the effect of mucoadhesive containing cinnamaldehyde extract on pain intensity of patients; Determination of the Effect of mucoadhesive Containing Cinnamaldehyde Extracts in the Process of Wound Inflammation ; Determine the effect of mucoadhesive containing the cinnamaldehyde extract during the recovery period of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180312039060N2**

Registration date: **2018-07-20, 1397/04/29**

Registration timing: **prospective**

Last update: **2018-07-20, 1397/04/29**

Update count: **0**

Registration date

2018-07-20, 1397/04/29

Registrant information

Name

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Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Cinnamaldehyde mucoadhesive effect on minor recurrent aphthous stomatitis		Postal code 4259-4886
Public title Assessment of Cinnamaldehyde effect on aphthous		Approval date 2017-12-22, 1396/10/01
Purpose Treatment		Ethics committee reference number IR.MAZUMS.RES.1396.10438
Inclusion/Exclusion criteria Inclusion criteria: patient with recurrent aphthous stomatitis Patients who have aphthous lesions in the lips and buccal mucosa Lack of systemic disease No use of denture No antibiotic use Exclusion criteria:		Health conditions studied 1 Description of health condition studied recurrent aphthous stomatitis ICD-10 code K12.0 ICD-10 code description Recurrent oral aphthae
Age From 20 years old to 40 years old		Primary outcomes 1 Description Determination of the Effect of Mucoadhesive Containing Cinnamaldehyde Extract on the Pain Intensity of Patients Timepoint 3 times a day after each meal Method of measurement Based on the VAS questionnaire
Gender Both		Secondary outcomes 1 Description Determine the effect of mucoadhesive containing the cinnamaldehyde extract in the process of wound inflammation Timepoint On the zero days (before entering the study) and 7 days later Method of measurement Using metal caliber to determine the diameter of the lesions and the inflammatory area around them
Phase 0		Intervention groups 1 Description Intervention group: Patients with recurrent aphthous stomatitis, aged 20 to 40 years old, all have a history of minor ulcerations in areas such as lobes and buccal mucosa. Category Treatment - Drugs
Groups that have been masked • Participant • Outcome assessor		Recruitment centers
Sample size Target sample size: 44		
Randomization (investigator's opinion) Randomized		
Randomization description Patients present in the study will be Simple randomly divided into two groups.		
Blinding (investigator's opinion) Double blinded		
Blinding description Due to the similarity of the mucoadhesives , none of the patients will know the nature of the adhesives. Also, the person who evaluates does not know the patient grouping		
Placebo Used		
Assignment Other		
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 Khazar blv. faculty of dentistry City Sari Province Mazandaran		

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Recruitment center

Name of recruitment center

Faculty of Dentistry, Mazandaran University of
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Full name of responsible person

Tahereh Molania

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Sponsors / Funding sources

1

Sponsor

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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

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

Alireza ebrahimpour

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

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