Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 mocoadhesive 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
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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

Public title
Assessment of Cinnamaldehyde effect on aphthous
Purpose
Treatment
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:
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Outcome assessor

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
Postal code
4259-4886
Approval date
2017-12-22, 1396/10/01
Ethics committee reference number
IR.MAZUMS.RES.1396.10438

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
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

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

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

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Dentistry, Mazandaran University of Medical Sciences

Full name of responsible person
Tahereh Molania

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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