Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluate the effectiveness of licorice extract to improve recurrent aphthous stomatitis (RAS)

Protocol summary

Summary

In the present study, the effect of mucoadhesive containing licorice extract on pain reduction and accelerating recovery of aphthous ulcers is reviewed. This study is randomized, double-blind and placebo controlled. The studied population is chosen among the referrers to oral and maxillofacial diseases division of faculty of dentistry of Mazandaran university of medical sciences in 2016/1395 and they will consciously sign the testimonial/disclaimer form. This clinical trial is performed on 18+ year-old patients with recurrent oral aphthous. The studied people will be randomly divided into two groups of “control” and “intervention”. The control group will get the mucoadhesive without the medication and the intervention group will get the mucoadhesive with licorice extract. The patients will be asked to use the mucoadhesive 3 times a day for a week. The patients` pain level will be recorded by themselves and the diameter of the ulcer with inflammatory halo will be recorded by the project executors using a periodontal probe in clinic. and in the end the results out of both of the groups will be compared to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031333046N1**
Registration date: **2017-04-16, 1396/01/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-16, 1396/01/27

Registrant information

Name

Aliakbar Sharifian

Name of organization / entity

Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, mazandaran university of medical science

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate the effectiveness of licorice extract to improve recurrent aphthous stomatitis (RAS)

Public title

effectiveness of licorice to improve aphthae

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Minimum age 18 years; have sufficient knowledge and literacy, oral aphthous ulcers. Exclusion criteria: major and recurrent stomatitis herpetiformis; aphthous ulcers and other patients who have the buccal mucosa and lips; systemic disease; those taking immunosuppressant drugs during the past month

denture wearers; recipients of antibiotics; pregnant patients; people who are not able to use the mucoadhesive; aphthous ulcer syndrome is that it is one presentations (Behcet); smokers and those who can not study continue until the end due to personal or social causes.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Mazandaran University of Medical Sciences

Street address
Vice chancellor for research, Mazandaran university of medical science, The martyr Motahhari square, Street teacher

City
Sari

Postal code

Approval date
2016-11-29, 1395/09/09

Ethics committee reference number
IR.MAZUMS.REC.95.2303

Health conditions studied

1

Description of health condition studied
Recurrent aphthous ulcers

ICD-10 code
K12.0

ICD-10 code description
recurrent aphthous stomatitis

Primary outcomes

1

Description
severity of pain

Timepoint
48 hours

Method of measurement
visual analoge scale

2

Description
The total size of the wound with erythematous halo

Timepoint
48 hours

Method of measurement
Periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description
Mucosal Adhesive 3 times a day for seven days

Category
Placebo

2

Description
Mucous adhesive containing licorice extract three times a day for seven days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Clinic, Mazandaran University of Medical Sciences

Full name of responsible person
Maedeh Salehi

Street address
Dental clinic, Khazar Blvd, Khazar square

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Vice chancellor for research, The martyr Motahhari square, Street teacher

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Tahereh Molania

Position

Professor / Associate Professor, School of Dentistry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty