

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of the effect of mucoadhesive containing mulberry (*Morus nigra* L.) fruit juice for treatment of minor recurrent aphthous stomatitis compared with placebo: a double blind randomized clinical trial

Protocol summary

Summary

The aim of this study is evaluation of the effect of mulberry fruit juice for treatment of minor recurrent aphthous stomatitis. this study is a randomized double blind clinical trial on 40 patients over 18 years of age with recurrent oral aphthous ulcer. The patients referring to the Department of oral and maxillofacial diseases, Faculty of Dentistry, Mazandaran University of Medical Sciences, will be divided into 2 groups of drug and placebo. All the patients will be instructed to use one mucoadhesive three times a day (morning, noon and evening) for seven days. the severity of pain by Visual Analogue Scale (VAS) and also the diameter of the ulcer with inflammatory halo by periodontal probe will be measured on days zero, three, five and seven after starting the treatment. Finally, The data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031129802N2**
Registration date: **2017-09-04, 1396/06/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

Somayeh Shahani

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology,
Mazandaran University of Medical Sciences

Expected recruitment start date

2016-08-23, 1395/06/02

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of mucoadhesive containing mulberry (*Morus nigra* L.) fruit juice for treatment of minor recurrent aphthous stomatitis compared with placebo: a double blind randomized clinical trial

Public title

Evaluation of mulberry juice in treatment of oral aphthous ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with minor aphthous stomatitis; over 18 years old. Exclusion criteria: major and recurrent stomatitis herpetiformis; patients who have aphthous ulcers other than buccal mucosa and lips; having 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 ulcers which are the manifestation of a syndrome (Behcet); smokers and those who can not complete the study until the end due to personal or social causes.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: Patients will be randomly divided into two groups of drug and placebo using a random number table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Moallem Square

City

Sari

Postal code**Approval date**

2016-08-22, 1395/06/01

Ethics committee reference number

IR.MAZUMS.REC.95.2080

Health conditions studied**1****Description of health condition studied**

Recurrent aphthous ulcer

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes**1****Description**

Severity of pain

Timepoint

Zero, three, five and seven days after the treatment

Method of measurement

Visual Analogue Scale

2**Description**

The total size of the ulcer with erythematous halo

Timepoint

Zero, three, five and seven days after the treatment

Method of measurement

Periodontal probe

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Mucoadhesive with mulberry juice, three times a day for seven days

Category

Treatment - Drugs

2**Description**

Intervention group 2: Mucoadhesive without medicine, three times a day for seven days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Maedeh Salehi

Street address

Department of oral and maxillofacial diseases, Faculty of Dentistry, Khazar Blvd.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

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Moallem square

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 and Technology,
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

Somayeh Shahani

Position

Assistant Professor, Department of Pharmacognosy
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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