

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

evaluation of the effect of caffeic acid on recurrent aphthous stomatitis improvement

Protocol summary

Study aim

Evaluation of the effect of caffeic acid on recurrent aphthous stomatitis improvement

Design

This clinical trial have two parallel group randomised with blinded postoperative care and with four block which have 2 patients of control and two patients of intervention group with the using of this site: ww.sealedenvelope.com/simple/randomise/v1/lists

Settings and conduct

Patients who suffering from aphthous and attend dental school, receiving a bottle of 21 caffeic acid mucoadhesive tablets. They should topically use them after each meal like morning, middle of the day and night. It is good to avoiding drinking or eating after using each tablet till one hour for better absorption.

Participants/Inclusion and exclusion criteria

Patients which suffering from recurrent aphthous stomatitis who are in the range of 20 to 40 years old and having aphthous minor ulcer in lips and mucobuccal area.

Intervention groups

In intervention group which receive mucoadhesive tablet containing caffeic acid, tablet is using topically on aphthous and towards releasing of it, it absorbs the mucosa. 25 patient are belong to this group. In control group patients receiving tablets which they are lack of caffeic acid. 25 patients individually will receive 21 tablets which are in the bottle. 21 tablets are for 7 days which every day morning, after lunch and afternoon should use them(totally 3 tablets for one day)

Main outcome variables

Severity of pain- amount of inflammation by using of diameter of erythematous layer around aphthous and number of days which healing occur

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220815055700N1**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Maede Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 4134

Email address

salehimaede1165@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-17, 1401/06/26

Expected recruitment end date

2022-10-21, 1401/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effect of caffeic acid on recurrent aphthous stomatitis improvement

Public title

evaluation of the effect of caffeic acid on recurrent aphthous stomatitis improvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

being infected to minor stomatitis aphthous type age range 20 to 40 having aphthous ulcer in lips and buccal area of the mouth having sufficient knowledge for understanding the testimonial

Exclusion criteria:

being infected to major or herpeti form having aphthous ulcer in other area except lips and buccal having systemic disease using immunosuppressive drugs having denture pregnant disease which having syndromes such as behcet's disease patients who smoke patient who cannot fill their testimonial

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to categorize samples into two groups we use randomize blocks method. Blocks will be consider as 4 (which in each group we have 2 patients of placebo and 2 patients of intervention). Selection the name of each group is according to this site:

www.sealenvelope.com/simple-randomise/v1/lists

Blinding (investigator's opinion)

Double blinded

Blinding description

Caffeic acid tablets for patients in exact similar bottle with a numeric code that provided by pharmaceuticals department of pharmacy school of medical university of Mazandaran

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

Khazar square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2022-08-12, 1401/05/21

Ethics committee reference number

IR.MAZUMS..REC.1401.14404

Health conditions studied

1

Description of health condition studied

Minor recurrent stomatitis aphthous

ICD-10 code

Recurrent

ICD-10 code description

K12.0

Primary outcomes

1

Description

Pain and inflammation

Timepoint

0 ,3,5 and 7 days after

Method of measurement

Visual analog scale for pain and diameter of erythematosis around aphthous due to inflammation

Secondary outcomes

1

Description

Duration of having aphthous

Timepoint

After 7 days

Method of measurement

Visual Analog Scale and dimeter of erythematosis

Intervention groups

1

Description

Intervention group: receiving mucoadhesive tablet which contain Caffeic acid

Category

Treatment - Drugs

2

Description

Control group: receiving mucoadhesive tablet which not contain any amount of Caffeic acid

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba dental clinic(dental school of Mazandaran)

Full name of responsible person

Maede Salehi

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Khazar Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnezhad

Street address

Tahghighar and Fanavari Institute- Shahid Motahari Square- Moallem St

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Fax

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Email

Pedrahimnejad@mazums.ac.ir

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

Full name of responsible person

دکتر مائده صالحی

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Maede Salehi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

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