Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 postoperetive 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 absoption.

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 absorpts 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 pharmaceutics 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 erythematosus 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 erythematosus

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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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
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Person responsible for updating data

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Dr Maede Salehi

Position
Associate professor

Latest degree
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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