Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Jujube-chicory-honey mouthwash effect on pain control and size of aphthous lesions in patients with recurrent aphthous stomatitis in comparison with Triadent .

Protocol summary

Study aim
Evaluation of the effect of jujube-chicory-honey mouthwash on pain and healing of recurrent aphthous stomatitis

Design
This study is a clinical trial in phase 2 with control group. It is designed as a parallel, double blinded and randomized evaluation. The total sample size is 24 patients.12 participants in the evaluation group and 12 participants in the control group will be enrolled. Patients with recurrent aphthous stomatitis will be divided randomly (block randomization) into 2 experimental and control groups. In experimental and control groups patients will receive jujube-chicory-honey mouthwash and oral paste Triadent 0.1% respectively, three times a day for 7days.

Settings and conduct
The patients who will be referred to Oral and Maxilllofacial Diseases Department of Shiraz Dental School with recurrent aphthous stomatitis will be enrolled. This study is double blinded. The outcome assessor and statistical analyzer will not know the type of prescribed treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having recurrent aphthous stomatitis, not using other routine medication for RAS during evaluation, less than 24 hours from lesion onset time, not using systemic or topical corticosteroid since 1 month ago. Exclusion criteria: The patients with Behcet disease, Crohn's disease, Reiter's syndrome, or any other inflammatory disease, pregnant women.

Intervention groups
Intervention group: Patients with recurrent aphthous stomatitis in the experimental group will receive jujube-chicory-honey mouthwash 3 times daily for 7 days. Control group: In the control group oral paste Triadent0.1% (Raha pharma. Isfahan-Iran) will be prescribed three times a day for 7 days

Main outcome variables
Pain, the size of lesion, healing period

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120101008585N15**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date
2022-04-03, 1401/01/14

Registrant information

Name
Fatemeh Lavaee

Name of organization / entity
Shiraz Dental School

Country
Iran (Islamic Republic of)

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+98 71 1631 9309

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lavaeef@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Jujube-chicory-honey mouthwash effect on pain control and size of aphthous lesions in patients with recurrent aphthous stomatitis in comparison with Triadent .

Public title

Jujube-chicory-honey mouthwash effect on pain and size of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having recurrent aphtus stomatis (RAS) Not using other routine medication for RAS during the evaluation Less than 24 hours from lesion onset time Not using systemic or topical corticosteroid since 1 month ago.

Exclusion criteria:

The participants with other diseases including Behcet disease, Crohn disease, Reiter's syndrome, or any other inflammatory disease The participants who have used analgesic mouthwash or systemic analgesia since 3 days ago pregnant women

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Each block with 4 allocations, consisting of 2 allocations for intervention and 2 for the control group will be considered. Six possible sequences of treatment allocation in each block will be listed. Each one was written on a card. Each time a block had been selected and the sequence of treatments was registered until the treatment allocations become completed for all 24 patients (6 blocks).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ghasrdasht

City

Shiraz

Province

Fars

Postal code

7195845379

Approval date

2020-09-06, 1399/06/16

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.187

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

Pain

Timepoint

Days 1, 2, 3, 4, 5, 6, 7 before and after treatment

Method of measurement

Visual anloge scale

2

Description

The size of lesion

Timepoint

Days 1, 2, 3, 4, 5, 6, 7 before and after treatment

Method of measurement

Degreed tongue blade

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with recurrent aphthous

stomatitis in the experimental group will receive jujube-chicory-honey mouthwash on recurrent aphthous stomatitis 3 times daily for 7 days.

Category

Treatment - Drugs

2

Description

Control group: In the control group oral paste Triadent0.1% (Raha pharma. Isfahan-Iran) will be prescribed three times a day for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dental School

Full name of responsible person

Fatemeh Lavaee

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Ghasrdasht, Mehr Ave., Shiraz Dental school

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Abbas Rezaianzade

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Statistical data file
When the data will become available and for how long
The data will be given to the requester by email up to 1 year after results registration.
To whom data/document is available
The data will be given to the requester by email up to 1 year after results registration.
Under which criteria data/document could be used
The data will be given to the requester by email up to 1 year after results registration.
From where data/document is obtainable
The data will be given to the academic requester by email up to 1 year after results registration.
What processes are involved for a request to access data/document
The data will be given to the academic requester by email up to 1 year after results registration.
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Comments