Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effect of Combined Herbal Mouthwash (Containing Thymus, Aloe vera, Glycyrrizha and Myrtus) on Oral Aphthous Lesions; A Triple-Blind Randomized Clinical Trial Study

Protocol summary

Study aim

Determining the effect of combined herbal mouthwash (containing Thymus, Aloe vera, Glycyrrizha and Myrtus) on oral aphthous lesions

Design

A clinical trial with a control group (with three groups), with parallel groups, three blinded, randomized, phase 3 on 90 patients (each group 30 patients). A table of random numbers is used for randomization.

Settings and conduct

In this study, 90 patients with minor oral aphthous lesions (within the first 48 hours of the onset of the lesion) who referred to the oral diseases department of Qazvin Dental Faculty, after receiving informed consent are randomly entered into one of the three study groups. Completely identical and coded containers are randomly given to patients by the department secretary, the evaluator and the patient are unaware of the mouthwash content. The size of the lesions is recorded by the periodontal probe and the pain of the patients using the VAS scale in the same meeting. On the third, fifth, and seventh days, the patient returns, and the size of the lesions and pain are measured. Patients are told to rinse their mouth with 10 ml of mouthwash for 1 minute 3 times a day after each meal until the lesion disappears and to avoid eating and drinking for 30 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with minor oral aphthous lesions, less than 48 hours have passed since the lesion. Exclusion criteria: Patients who are allergic to medicinal plants or have systemic diseases (High blood pressure, Diabetes, Hyperlipidemia, Behcet's disease, Rheumatic disease).

Intervention groups

The first group: receive combined herbal mouthwash (containing Thymus, Aloe vera, Glycyrrizha and Myrtus) The second group: receive mouthwash containing triamcinolone. The third group (control): receive placebo mouthwash.

Main outcome variables

1) Size of lesion 2) Pain level 3) Healing duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220522054957N1**
Registration date: **2022-08-24, 1401/06/02**
Registration timing: **prospective**

Last update: **2022-08-24, 1401/06/02**
Update count: **0**

Registration date

2022-08-24, 1401/06/02

Registrant information

Name

Benyamin Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Combined Herbal Mouthwash (Containing Thymus, Aloe vera, Glycyrrizha and Myrtus) on Oral Aphthous Lesions; A Triple-Blind Randomized Clinical Trial Study

Public title

The Effect of Combined Herbal Mouthwash (Containing Thymus, Aloe vera, Glycyrrizha and Myrtus) on Oral Aphthous Lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Oral aphthous lesions less than 48 hours have passed since the lesion Oral aphthous lesions are of minor type The age of patients should be between 18 and 60 years

Exclusion criteria:

Having systemic diseases Drug use, smoking, alcohol and drug addiction Patient sensitivity to medicinal plants

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method is used with the help of a table of random numbers.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient, the evaluator (researcher) as well as the data analyst are not aware of the type of mouthwash received by the patient. Mouthwash containers have the same shape and color and are given to patients by another person.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

No. 9, Shahaamat Alley., Modarres Blvd

City

Qazvin

Province

Qazvin

Postal code

3413815164

Approval date

2022-08-12, 1401/05/21

Ethics committee reference number

IR.QUMS.REC.1401.130

Health conditions studied

1

Description of health condition studied

Oral aphthous lesions

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Pain level of oral aphthous lesions

Timepoint

Measuring the pain level of oral aphthous lesions at the beginning of the study (before the start of the intervention) and 3, 5 and 7 days after the start of using the mouthwash

Method of measurement

By the Visual Analogue Scale

2

Description

Size of oral aphthous lesions

Timepoint

Measuring the size of oral aphthous lesions at the beginning of the study (before the start of the intervention) and 3, 5 and 7 days after the start of using the mouthwash

Method of measurement

By periodontal probe

3

Description
Healing duration of oral aphthous lesions
Timepoint
Examining the healing of oral aphthous lesions after starting to use mouthwash, on days 3, 5 and 7 or more, until the day when the lesion is completely healed.
Method of measurement
Calendar

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: This group uses a combined herbal mouthwash containing Thymus, Aloe vera, Glycyrrizha and Myrtus with a concentration of 4%, which was prepared in the Biotechnology Laboratory of Qazvin University of Medical Sciences and formulated in Alborz Darou Company of Qazvin until the aphthous lesion disappears. In this way, 3 times a day (after each meal), 10 ml of mouthwash is used for 1 minute and they avoid eating and drinking for 30 minutes after that.
Category
Treatment - Drugs

2

Description
The second intervention group: This group uses Triamcinolone mouthwash with a concentration of 0.1%, which is made in Alborz Darou Company of Qazvin, until the aphthous lesion disappears. In this way, 3 times a day (after each meal), 10 ml of mouthwash is used for 1 minute and they avoid eating and drinking for 30 minutes after that.
Category
Treatment - Drugs

3

Description
Control group: This group uses placebo mouthwash until the aphthous lesion disappears. In this way, 3 times a day (after each meal), 10 ml of mouthwash is used for 1 minute and they avoid eating and drinking for 30 minutes after that.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Qazvin University of Medical Sciences
Full name of responsible person
Benyamin Kazemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr Seyyed Mehdi Mirhashemi
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person

Benyamin Kazemi
Position
student
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