

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the Effectiveness of Bamboo Salt mouthwash compared to Non-Steroidal mouthwash in the improvement of Recurrent Aphthous Ulcers, a Double Blind Randomized Clinical Trial

Protocol summary

Study aim

Determining and comparing the healing indices of recurrent minor aphthous ulcers using bamboo salt mouthwash and non-steroidal benzydamine mouthwashes.

Design

A randomized, blinded, sham controlled clinical trial with a parallel group design of 40 patients, Randomisation was centralised using Block Randomization method

Settings and conduct

20 individuals randomly received the bamboo salt mouthwash and benzydamine and the other 20 received benzydamine and normal saline. After receiving instructions, the patients are asked to record the aphthous pain level on days 0, 1, 3, and 5 based on visual analogue scale (VAS) using a number from 0 to 10. Moreover, they are informed to record the date of pain elimination and pseudomembrane removing. The time when the pseudomembrane and the erythematous border are removed is regarded as the complete healing date. During the treatment, researchers are constantly in contact with the patients to ensure they are following the instructions, recording the results correctly, and determining any adverse reactions. After 1 week, the patients will be examined again and the questionnaires are collected. At the end of the study the bottles will be decoded. The patients and researcher are blinded in this study.

Participants/Inclusion and exclusion criteria

Patients with minor aphthous lesions less than 2 days from initiation. The individuals who had not suffered from systemic diseases or immunologic disease. Patients who have not been receiving Anti-inflammatory, Antibiotics, sedative or immunosuppressive drugs for at least 2 weeks before the study begins

Intervention groups

The experimental group receives Benzydamine

mouthwash and Bamboo salt mouthwash. The control group receives Benzydamine mouthwash and Normal saline.

Main outcome variables

Duration of pseudomembrane removing; The size; The degree of pain of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160126026209N3**

Registration date: **2023-04-15, 1402/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

zahra saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-08, 1402/01/19

Expected recruitment end date

2023-06-13, 1402/03/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Bamboo Salt mouthwash compared to Non-Steroidal mouthwash in the improvement of Recurrent Aphthous Ulcers,a Double Blind Randomized Clinical Trial

Public title
Evaluation of the effectiveness of Bamboo Salt mouthwash in the improvement of Recurrent Aphthous Ulcers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with minor aphthous lesions less than 2 days from initiation The individuals who had not suffered from systemic diseases or immunologic disease The patient should not receive other concurrent medication for aphthous ulcers either systematically or locally at the same time with this medicine Patients who had a history of frequent recurrence of aphthous lesions The occurrence of aphthous lesions is not caused by beta blockers and NSAIDs Patients who dose not being in pregnancy or breastfeeding time Patients who have not been receiving Anti-inflammatory or immunosuppressive drugs for at least 2 weeks before the study begins Patients who have not been receiving systemic Antibiotics for at least 2 weeks before the study begins Have not treated aphthous ulcers with any other medicine in the last 3 days Patients who have not been receiving sedative medicine for other diseases
Exclusion criteria:
In case of sudden problem or violation of Inclusion criteria, the patient will be excluded from the study

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly assigned(using Block Randomization method using Quadruple Blocks) into experimental and placebo groups (20 patients per each group). The products were placed in exactly similar

containers and were coded by a third person, so that 20 individuals randomly received the Bamboo Salt mouthwash and Benzydamine and the other 20 received Benzydamine and Normal saline.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients and researcher are blinded in this study. Participants are informed that they will randomly receive Benzydamine and Bamboo Salt mouthwash or Benzydamine and Normal saline. The products (Bamboo Salt mouthwash and Normal saline) were placed in exactly similar containers and were coded by a third person! so that the researcher and the participant are not aware of the received medicine received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

No.1,102 Alley., Amirkabir Ave

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Postal code

8417643471

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.348

Health conditions studied

1

Description of health condition studied

recurrent aphthous ulcers

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Duration of lesion's pseudomembrane removing

Timepoint

The time when the pseudomembrane and the erythematous border are removed

Method of measurement

Observing the lesion

2

Description

The size of the lesion

Timepoint

The aphthous lesion size will be recorded on days 0, 1, 3, and 5

Method of measurement

Periodontal probe

3

Description

The aphthous pain level

Timepoint

The patients are asked to record the aphthous pain level on days 0, 1, 3, and 5

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gargle 60 cc (containing 30 cc of 10% bamboo salt and 30 cc of benzydamine 0.15%) solution every 8 hours and avoid eating and drinking for at least 30 to 60 minutes after use.

Category

Treatment - Drugs

2

Description

Control group: Gargle 60 cc (containing 30 cc normal saline 0.9% and 30 cc of benzydamine 0.15%) solution every 8 hours and avoid eating and drinking for at least 30 to 60 minutes after use.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental School

Full name of responsible person

Dr.Zahra Saberi

Street address

Oral and Maxillofacial department, School of Dentistry, Isfahan University of Medical Sciences School of Dentistry, St.Hezarjarib, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Askari

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Research and Technology Vice Chancellor, Building No. 4, Isfahan University of Medical Sciences School, St.Hezarjarib, Isfahan

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Zahra Saberi
Position
Assistant 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

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Questionnaires and information recorded by the researcher can be published

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For use in other research and any reanalysis

From where data/document is obtainable

Dr.Zahra Saberi tel:00989133164817
Email:zahra.saberi@dnt.mui.ac.ir

What processes are involved for a request to access data/document

Examining the purpose of the request and the researcher's information

Comments