

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the palliative effects and stability of Diphenhydramine-Almgs versus 0.1% Teriadent oral paste in patients with Recurrent Aphthous Stomatitis

Protocol summary

Study aim

Assessment of physical stability and function of the combined solution in reducing pain and burning and its acceptance by clients

Design

Clinical trial study, with parallel groups

Settings and conduct

This study was performed on 50 patients referring to Apadana Dental Clinic with multiple oral aphthous lesions divided into two groups of 25 each. The first group received diphenhydramine-Almgs solution and the second group received 0.1% triadent oral paste. Then the physical stability of the combined solution will be assessed and the two groups will be compared regarding the duration of the wound healing, the rate of pain and burning (VAS criterion) and ultimately the patients' satisfaction.

Participants/Inclusion and exclusion criteria

Entry requirements: Multiple aphthous ulcers (more than 1) that appeared in the mouth less than 48 hours. People over 18 years; Exit conditions: A well-known history of increased drug sensitivity Systemic diseases such as Behcet, Crohn's disease, thalassemia Vitamin B12 deficiency and iron deficiency Pregnant and lactating women smokers Taking oral antihistamine or non-steroidal anti-inflammatory drugs over the past week Aphthous ulcers adjacent to trauma caused by sharp teeth, fractured healing, orthodontic appliance or partial prosthesis

Intervention groups

Intervention group: Diphenhydramine-Almgs solution was washed 3 times daily, 10cm for one minute, then mouthwashed and avoided eating for half an hour thereafter. Control group: Teriadent oral paste rubbed on the lesion 3 times daily, and avoid eating and drinking for up to half an hour.

Main outcome variables

1. Comparison of the analgesic effect and the VAS score of pain and burning in the two groups receiving the combination solution and oral paste 2. Determine patients' satisfaction with the combination of oral solution and paste 3. Comparison of the recovery time of RAS in the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N4**

Registration date: **2020-01-19, 1398/10/29**

Registration timing: **retrospective**

Last update: **2020-01-19, 1398/10/29**

Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-10-07, 1398/07/15

Trial completion date

2019-10-07, 1398/07/15

Scientific title

Comparison of the palliative effects and stability of Diphenhydramine-Almgs versus 0.1% Teriident oral paste in patients with Recurrent Aphthous Stomatitis

Public title

Comparison of the palliative effect of Diphenhydramine-Almgs versus 0.1% Teriident oral paste in patients with Recurrent Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Multiple aphthous ulcers (more than 1) that appeared in the mouth less than 48 hours. People over 18 years

Exclusion criteria:

A well-known history of increased drug sensitivity
Systemic diseases such as Behcet, Crohn's disease, thalassemia Vitamin B12 deficiency and iron deficiency
Pregnant and lactating women smokers Taking oral antihistamine or non-steroidal anti-inflammatory drugs over the past week
Aphthous ulcers adjacent to trauma caused by sharp teeth, fractured healing, orthodontic appliance or partial prosthesis

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Islamic Azad University of Tehran

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no. 165, Golsar Blvd.

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4166733658

Approval date

2018-06-13, 1397/03/23

Ethics committee reference number

IR.IAU.PS.REC.1397.323

Health conditions studied**1****Description of health condition studied**

Recurrent Aphthous Stomatitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Recurrent pest as one of the most common oral mucosal diseases is a recurrent and painful disease that, due to the unclear etiology and lack of definitive treatment, requires repeated periods of treatment and use of drugs with minimal local or systemic complications. has it.

Timepoint

At the beginning of the study, the third and seventh days

Method of measurement

Questionnaire and pH meter to evaluate the pH changes of the combined solution

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group received 10 ml of the solution of mouthwash 3 times daily for one minute, then mouthwashed and avoided eating for half an hour thereafter. On the third and seventh days, patients' statements about time to relieve pain and complete wound healing were recorded by a questionnaire.

Category

Treatment - Drugs

2

Description

Control group: The group rubbed the oral paste as a thin layer with a clean finger or applicator three times daily, avoiding eating and drinking for half an hour. On the third and seventh days, patients' statements about time to relieve pain and complete wound healing were recorded by a questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Apadana dental clinic

Full name of responsible person

Mahtab ghamgosar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mahtab Ghamgosar

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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