

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of effectiveness of the Bioadhesive paste Containing Licorice 5% with Bioadhesive Paste without drug in the Management of Recurrent Aphthous Stomatitis

Protocol summary

Summary

The present study was aimed to assess the efficacy of the application of licorice bioadhesive paste 5% to the pain control and reduce the healing time of RAS ulcer. A total of 60 of patients With history of recurrent aphthous stomatitis, referred to the School of Dentistry in zahedan, were recruited and assigned into one of the three following groups. The Patients received Diphenhydramine Elixir, Bioadhesive paste without licorice, or paste with licorice, (four times daily for 5 days). Size of ulcer, the necrosis diameter, and pain intensity were measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011273133N2**

Registration date: **2011-01-31, 1389/11/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

Name

Fateme Arbabi Kalati

Name of organization / entity

Dental school of Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 1814

Email address

farbabi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2010-06-04, 1389/03/14

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of the Bioadhesive paste Containing Licorice 5% with Bioadhesive Paste without drug in the Management of Recurrent Aphthous Stomatitis

Public title

Comparison of effectiveness of the Bioadhesive paste Containing Licorice 5% with Bioadhesive Paste without drug in the Management of Recurrent Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of recurrent aphthous stomatitis, Current suffering from ulceration in 1 day, signed a well-explained written informed consent form
Exclusion criteria: Pregnancy, lactation (Urine hCG-positive), Ulcers as a manifestation of a systemic disease process such as ulcerative colitis, Crohn's disease, Behcet's syndrome, serious anemia, treatment with systemic steroid or other immunomodulatory agents within 1 month before the study entry, ulcer in tongue, major RAS, presenting with more 1 aphthous ulcers, after

24 hours' duration of ulcer

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Dr. Hesabi Square

City

Zahedan

Postal code

892096

Approval date

2010-10-27, 1389/08/05

Ethics committee reference number

892096

Health conditions studied

1

Description of health condition studied

Recurrent aphthous stomatitis

ICD-10 code

K12.0

ICD-10 code description

recurrent aphthous stomatitis

Primary outcomes

1

Description

diameter of the lesion with erythematous rim

Timepoint

48 hours

Method of measurement

periodontal prob

2

Description

diameter of necrotic zone

Timepoint

48 hours

Method of measurement

periodontal prob

3

Description

pain level

Timepoint

48 hours

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bioadhesive paste Containing Licorice 5% 4 times per days 1h before meal and 20 minutes before sleep

Category

Treatment - Drugs

2

Description

Control group: diphen hydramin elixir, 5 cc, 4 times per days 1h before meal and 20 minute before sleep

Category

Treatment - Drugs

3

Description

Control group: Bioadhesive paste without Licorice 5%, 4 times per days 1h before meal and 20 minute before sleep

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Zahedan University of Medical Sciences,
Full name of responsible person
Narjes Akbare
Street address
Zahedan University of Medical Sciences
City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Narjes Akbare
Street address
School of Dentistry of Zahedan
City
Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences,
Full name of responsible person
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Email
narges_akbare4021@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty