

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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: diphenhydramin 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
Narges 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
Narges 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
Narges Akbare
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Web page address

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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