Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the efficacy of Alum mucosal adherent in management of wound size of Recurrent Aphthous Stomatitis in Hamadan dental faculty in comparison with placebo group

Protocol summary

Summary

The aim of this study is determination of efficacy of alum in management of pain, size and duration of ulcer healing in subjects with oral Aphtous ulcer in comparison with Placebo. In this double blind experimental clinical trial , 50 patients 15 to 24 years old, with history of minor oral aphtous in buccal and labial mucosa that attendant to oral medicine department of Hamadan dental faculty and volunteer students will be selected. The base of mucosal adherent in both groups include gum tragacanth, Alchohol, Water, and Sodium Benzoat. In study group Alum will be added to mucosal adherent. According to administration order, subjects should apply the adherent 3 times a day for 5 days in equal periods for 20 minutes on their aphtous ulcers. Subjects will be followed After one, three and five days. Healing criteria are size, pain and duration of healing of ulcers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305275678N2**
Registration date: **2014-06-12, 1393/03/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-12, 1393/03/22

Registrant information

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Hamidreza Abdolsamadi
Name of organization / entity
Faculty of dentistry
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Science

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Alum mucosal adherent in management of wound size of Recurrent Aphthous Stomatitis in Hamadan dental faculty in comparison with placebo group

Public title

Evaluation of the efficacy of Alum in wound size of oral Aphthous

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for inclusion : people (male or female) over 15 years,The patient had a history of aphtous (at least 3 times a year), have a lesion less than 10 mm diameter,This ulcer must be in the areas of the mouth, which can be easily used in medicine including the tongue, floor of the mouth and the lining of the cheek

Mucosa, lbial. should be a maximum of 3 days begining of new lesions (new lesion) ,no history of tratment Exclusion criterias:pregnancy or lactating subjects ,patients with systemic diseases associated withAphtous like Cron,Rhiter and Behcet's disease ,consumption of chewable tobacco or cigarettes and ,Viral and fungal diseases , treatment with any other drug, consumption of acetaminophen and NSAID'S orantihistamine or another medication to treat thelesions, oral surgery over the past two weeks , orthodontic wire and bracket or restorative treatment

Age
From **15 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Vice President for research and technology

Street address
Hamedan- University of medical sciences

City
Hamedan

Postal code
65178-38677

Approval date
2013-05-02, 1392/02/12

Ethics committee reference number
پ/د/16/35/9/286

2

Ethics committee

Name of ethics committee
Vice President for research and technology

Street address
Hamedan-university of medical sciences

City
Hamedan

Postal code
65178-38677

Approval date
2013-05-02, 1392/02/12

Ethics committee reference number
پ/د/16/35/9/286

Health conditions studied

1

Description of health condition studied
recurrent aphtous stomatitis

ICD-10 code
k12.0

ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
the size of the wound

Timepoint
days1,3,5

Method of measurement
ruler

Secondary outcomes

1

Description
the intensity of the pain

Timepoint
days 1,3,5

Method of measurement
visual analogue scale

Intervention groups

1

Description
Case group:"Aplication of mucous Adhesives containing alum" Control group: "Application ofadhesive without alum(placebo) "

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
dental faculty

Full name of responsible person

Dr hamidrezaabdolsamadi

Street address

Hamedan_dentalfaculty

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research center

Full name of responsible person

Dr Shahin Kasrayi

Street address

Hamadan dental faculty

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

research center

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

dental faculty-departmant of oral medicine

Full name of responsible person

Dr Shahrbanou Raedi

Position

assistant proffessor

Other areas of specialty/work

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Person responsible for updating data

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dental faculty

Full name of responsible person

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Position

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Other areas of specialty/work

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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