

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of mucoadhesive paste contains olive leaf extract in the treatment of Recurrent Aphthous stomatitis (RAS) compared with topical corticosteroid

Protocol summary

Summary

In this research effects of mucoadhesive paste contains olive leaf extract on treatment of aphthous ulcers compared to tropical corticosteroid drug is investigated. All patients with recurrent aphtus ulcers referring to clinic of dentistry school, Zahedan University of Medical Sciences who have the inclusion criteria and have not exclusion criteria are entered in this research. The patients with RAS are assigned to treatment group (mucoadhesive paste contains Olive leaf extract), Tropical glucocorticoid (mucoadhesive paste contains triamcinolone) and placebo group (mucoadhesive paste without any drug) by using a computer-generated random number list (N=26 in each group). The treatment and the placebo agents were packed in identical looking containers and labeled with a code number A or B or C randomly (named agents A, B and C) and the patient and dentist are blinded about the groups. Instruction of drug usage in all groups is 4 times per day, 3 times prior each meal and the last time, 20 min prior the sleeping. Evaluation and photography of ulcers are done in 0, 1, 2, 5 and 7th days from beginning of the experiment. Area of ulcer is estimated using Cavalieri's point counting method and to evaluate pain, a visual analog scale (VAS) is used. The effectiveness indices of the ulcer size and pain improvement are calculated with the formula and comparisons are done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080723542N1**

Registration date: **2015-09-12, 1394/06/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-12, 1394/06/21

Registrant information

Name

Zahra Heidari

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5796

Email address

heidari@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Grant from Zahedan University of Medical Sciences

Expected recruitment start date

2015-09-30, 1394/07/08

Expected recruitment end date

2016-04-30, 1395/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of mucoadhesive paste contains olive leaf extract in the treatment of Recurrent Aphthous stomatitis (RAS) compared with topical corticosteroid

Public title

Effects of mucoadhesive paste contains olive leaf extract in the treatment of Recurrent Aphthous stomatitis (RAS)

compared with topical corticosteroid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having 1-5 minor aphthous ulcer and their ulcers diameter were less than 5mm; having pain, without unusual sense of paresthesia and anesthesia; filling informed consent form for participation in this study. Exclusion criteria: having a history of drug hypersensitivity; pregnancy and breast feeding; having the history of systemic disorders or Behcet,s syndrome; receiving any other drug comprising NSAIDs or antihistamines in last 1 month; receiving any other drug for curing the ulcers from 72 hours prior the beginning the study; receiving systemic antibiotics from 2 weeks prior the beginning the study; Aphthous ulcers nearby trauma from sharp-edged teeth, broken restorations, orthodontic appliance or partial denture

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **26**

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

Ethic committee of Zahedan University of Medical Sciences

Street address

Pardis of Zahedan University of Medical Sciences

City

Zahedan

Postal code

98168-43175

Approval date

2015-08-02, 1394/05/11

Ethics committee reference number

IR.ZAUMS.IRC.1394.219

Health conditions studied

1

Description of health condition studied

Recurrent oral Aphthous

ICD-10 code

K12.0

ICD-10 code description

Recurrent aphthous ulcer

Primary outcomes

1

Description

surface of the ulcer

Timepoint

days 0, 1, 2, 5, and 7

Method of measurement

by stereological method of point counting method of cavalieri on ulcer photographs

2

Description

pain

Timepoint

days 0, 1, 2, 5, and 7

Method of measurement

VAS ruler of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mucoadhesive paste contains Olive leaf extract. Instruction of drug usage is 4 times per day, 3 times prior each meal and the last time, 20 min prior the sleeping. Evaluation and photography of ulcers are done in 0, 1, 2, 5 and 7th days from beginning of the experiment. Area of ulcer is estimated using Cavalieri's point counting method and to evaluate pain, a visual analog scale (VAS) is used.

Category

Treatment - Drugs

2

Description

Positive control group:Tropical glucocorticoid (mucoadhesive paste contains triamcinolone) with the same instruction that used in interventional group.

Category

Treatment - Drugs

3

Description

Negative control group: mucoadhesive paste without any drug with the same instruction that used in interventional group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Zahra Heidari

Street address

School of Dentistry, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Research and Technology of Zahedan University of Medical Sciences

Full name of responsible person

Dr Rafighdoost

Street address

Padis of Zahedan University of Medical sciences

City

Zahedan

Grant name

گرنٲ

Grant code / Reference number

7427

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

Yes

Title of funding source

Vice chancellor of Research and Technology of 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

Dr. Zahra Heidari

Position

Ph.D/ Pofessor

Other areas of specialty/work

Street address

School of Medicine, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Postal code

98168-43175

Phone

+98 54 3329 4390

Fax

+98 54 3329 4390

Email

histology@ymail.comhistology_iri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Zahra Heidari

Position

Ph.D/ Professor

Other areas of specialty/work

Street address

Histology department, School of medicine, Zahedan University of Medical Sciences, Zahedan

City

Zahedan

Postal code

98168-43175

Phone

+98 54 3329 4390

Fax

+98 54 3329 4390

Email

histology@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Zahra Heidari

Position

Ph.D/Professor

Other areas of specialty/work

Street address

Histology department, School of medicine, Zahedan
University of Medical Sciences, Zahedan

City

Zahedan

Postal code

98168-43175

Phone

+98 54 3329 4390

Fax

+98 54 3329 4390

Email

histology@ymail.com; histology_iri@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