

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Randomized comparative clinical trial of topical triamcinolone in orabase (Adcortyle) and Myrtus communis (Myrtex) 5% solution for the treatment of aphthous ulcer

Protocol summary

Summary

The aim of this study is to compare the therapeutic effect of topical triamcinolone in orabase with Myrtus communis topical solution for the treatment of aphthous stomatitis. The study encompasses all the patients with minor aphthosis referring to the private office and sample size includes 100 patients which will be divided into intervention and control groups based on randomized blocking method. Inclusion criteria: 1- age range: 18-50 years, 2- size of lesions: 2-4 mm in diameter, 3- number of lesions: 1-5. Exclusion criteria: 1- pregnancy, 2- lactation, 3- present history of any malignancy, 4- Behcet's syndrome. This study was approved by Ethical Review Committee of Kurdistan University of Medical Sciences. After informed consent the intervention group will use 5% Myrtus communis topical solution 10 drops on the lesions for 20 second, 5 times/day. Control group will use topical triamcinolone in orabase 4 times/day on the lesions. The patients were followed one week after treatment for assessment of pain relief and healing of the mucosal lesions by a dermatologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801201802N1**
Registration date: **2009-11-07, 1388/08/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-11-07, 1388/08/16

Registrant information

Name

Farrokh Rad

Name of organization / entity

Kurdistan University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2008-08-22, 1387/06/01

Expected recruitment end date

2009-06-22, 1388/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized comparative clinical trial of topical triamcinolone in orabase (Adcortyle) and Myrtus communis (Myrtex) 5% solution for the treatment of aphthous ulcer

Public title

The comparison of topical corticosteroid and Myrtex solution in the treatment of aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- age range: 18-50 years, 2- size of

lesions: 2-4 mm in diameter, 3- number of lesions: 1-5.
Exclusion criteria: 1- pregnancy, 2- lactation, 3- present history of any malignancy, 4- Behcet's Syndrome

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committee of Kurdistan University of Medical Sciences

Street address

Pasdaran St.

City

Sanandaj

Postal code

Approval date

2008-07-15, 1387/04/25

Ethics committee reference number

3755۲14۲

Health conditions studied

1

Description of health condition studied

Oral aphthous ulcer

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Pain relief

Timepoint

one week after treatment

Method of measurement

history of the patients

2

Description

Healing of the aphthous ulcer

Timepoint

one week after treatment

Method of measurement

clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Myrtus communis topical solution 10 drops, 5 times/day for 20 seconds on the lesions

Category

Treatment - Drugs

2

Description

Control group: Topical triamcinolone in orabase, four times/day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office

Full name of responsible person

Dr. Farrrokh Rad

Street address

Morvarid building, Pasdaran St.

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Ataollah Haydari
Street address
 Pasdaran St.
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 Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Kurdistan 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

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Name of organization / entity
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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