Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 aphthousis 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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dr_farokh.rad@muk.ac.ir

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 Commiitee 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
3755پ14پ

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. Farrokh 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.

City

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

Contact

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Farrokh Rad

Position

Dermatologist, Assistant proffessor of dermatology department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Farrokh Rad

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Assistant proffessor of dermatology department

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Farokh Rad

Position

Dermatologist, Assistant Proffessor of dermatology department

Other areas of specialty/work

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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