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
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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
None
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
Country
Iran (Islamic Republic of)
Postal code
Approval date
2008-07-15, 1387/04/25
Ethics committee reference number
3755

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

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
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Ataollah Haydari
Street address
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Country
Iran (Islamic Republic of)
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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Fax
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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