Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of two different topical corticosteroids in treatment of symptomatic oral lichen planus.

Protocol summary

Summary

In this clinical trial the patients with symptomatic oral lichen planus will be enrolled following signing the informed consent. Basic information and data are: age, gender, location, size, severity of symptoms and the size will be measured with posing a clear paper on lesions & detect the margins then pose it on scaled paper. Severity of symptoms will be assessed with visual analog scale. The patients will be randomly assign two groups, 22 persons with drug A and 22 person with drug B. The medications in this study are prepared with cooperation of pharmacologist & marked with A & B. Drug A consist of mouthwash dexamethasone 0.1% (15cc normal saline plus 5cc amp 8mg/ml2) and the other consist of mouthwash triamcinolon acetonide 0.2%(19cc normal saline plus 1cc amp 40mg/mm2) manufactured by Iran Hormone Co. Patients will wash their mouth 5 minutes, 4 times a day after meals & before sleep for four weeks. At the first, second and fourth week of the study, size of lesions & VAS will be measured and the result will be compared between study groups

General information

Acronym

Efficacy of topical corticosteroid in treatment of oral lichen planus

IRCT registration information

IRCT registration number: **IRCT201011275256N1**
Registration date: **2011-05-30, 1390/03/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-30, 1390/03/09

Registrant information

Name

Fatemeh Owlia

Name of organization / entity

Yazd shahid sadoughi dentistry faculty

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2010-10-26, 1389/08/04

Expected recruitment end date

2011-06-19, 1390/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two different topical corticosteroids in treatment of symptomatic oral lichen planus.

Public title

Efficacy of topical corticosteroid in treatment of oral lichen planus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Oral lichen planus patients confirmed with incisional biopsy; their lesions must be symptomatic; they shouldn’t have any systemic disease; not using drug with the side effect of lichenoid reaction

and the lesions should not be near amalgam dental restoration. Exclusion criteria: Patient cease their treatment or do not come on affirmed time.

Age
From **19 years** old to **78 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

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
Vice-Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address
Research Department, Building No 2,

City
Yazd,

Postal code
8916978477

Approval date
2010-10-25, 1389/08/03

Ethics committee reference number
17/1/79707پ

Health conditions studied

1

Description of health condition studied
Oral lichen planus

ICD-10 code
L43.8

ICD-10 code description
Other lichen planus

Primary outcomes

1

Description
Level of burning sensation

Timepoint
Weekly until 4weeks

Method of measurement
Visual Analog Scale

2

Description
Size of lesions

Timepoint
Weekly until 4weeks

Method of measurement
Scaled paper 1mm2

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: mouthwash dexamethasone 0.1%, patients areasked to wash 5 minutes their mouth 4 times daily after meals & before sleep for 4 weeK.it is prepared from mixing 5cc amp dexamethasone 8mg/2ml with 15 cc normal salin.

Category
Treatment - Drugs

2

Description
Second intervention group: mouthwash triamcinolon acetonide 0.2%, patients are asked to wash 5 minutes their mouth 4 times daily after meals & before sleep for 4 weeks . it is prepared from mixing 1cc amp triamcinolon acetonide 40mg/ml with 19 cc normal salin.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Faculty, Yazd Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
dr Fatemeh Ezoddini
Street address
Research Department, Building No 2,
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research, Yazd Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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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Person responsible for updating data

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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