

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 acetoneide 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)

Phone

+98 35 1621 2222

Email address

dr.olia@ssu.ac.ir

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 are asked 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 saline.

Category

Treatment - Drugs

2

Description

Second intervention group: mouthwash triamcinolon acetate 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 acetate 40mg/ml with 19 cc normal saline.

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,

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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

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for scientific inquiries

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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