

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial of comparative evaluation of effect of Beclomethasone and Adcortyle in treatment of Oral Lichen Planus

Protocol summary

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Summary

Abstract Objective: The aim of this study was comparative evaluation of effect of Beclomethasone and Adcortyle in Treatment of Oral Lichen Planus **Design:** single blind clinical trial **Method:** The target population for study was the patient with histologically documented to have oral lichen planus. **Criteria for inclusion:** All patients had symptomatic bilateral erosive or ulcerative oral lichen planus with similar intensity. **Criteria for exclusion:** Patients that were not cooperative, Use of another topical or systemic corticosteroid during the study **Sample volume:** This research was carried out on 19 patients. **Interventions:** Adcortyle, Beclomethasone. **Main outcom:** REU, VAS, kaliakatsoau.

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2009-08-16, 1388/05/25

Expected recruitment end date

2010-09-27, 1389/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101245678N1**

Registration date: **2011-07-02, 1390/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-02, 1390/04/11

Registrant information

Name

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Name of organization / entity

Faculty of dentistry

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Email address

Scientific title

Clinical trial of comparative evaluation of effect of Beclomethasone and Adcortyle in treatment of Oral Lichen Planus

Public title

Evaluation of two type corticosteroids in Treatment of Oral Lichen Planus

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for inclusion: All patients had symptomatic bilateral erosive or ulcerative oral lichen planus with similar intensity, Not used any systemic or topical corticosteroid, Written informed consent was obtained **Criteria for exclusion:** Patients that were not cooperative , use of another topical or systemic during the study

Age

From **33 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 19

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

Ethic committi of "Shahid Beheshti dental faculty"

Street address

Student BLV, Evin freeway, Tehran

City

Tehtran

Postal code

19839

Approval date

2009-03-03, 1387/12/13

Ethics committee reference number

277

Health conditions studied

1

Description of health condition studied

Lichen planus

ICD-10 code

L43

ICD-10 code description

Diseases of the skin and subcutaneous tissue

Primary outcomes

1

Description

Scaling of lesion

Timepoint

3-6-12 weeks

Method of measurement

REU

2

Description

Pain

Timepoint

3-6-12 weeks

Method of measurement

VAS (Visual Analuge Scaling)

3

Description

Raughness

Timepoint

3-6-12 weeks

Method of measurement

VAS

4

Description

Maximum diameter of lesion

Timepoint

3-6-12 weeks

Method of measurement

periodental prob(millimeter)

Secondary outcomes

1

Description

Candidiasis, Mucosal atrophy

Timepoint

3-6-12 weeks

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Adcortyle was used for treatment of control side. This paste is one of the appropriate drug in treatment oral lichen planus, so used to compare with treatment effect of Bechlomethason spray in oral lichen planus lesions . Adcortyle contains triamcinolone 0.01% in a adhesive carrier (methyl cellulose). Dose of drug was 3 times a day. Patients first dried side of lesion then covered the lesion with paste and eat anything for one hour.

Category

Treatment - Drugs

2

Description

Intervention in this article is treatment of oral lichen planus lesions with nasal spray Bechlomethasone dipropionate. Dose of drug was 50ugr/paff and used 4 times a day(2 puff in each time) after meals and before sleep. Patient was demonstrated that spray must closed to lesion and sprayed 2 paff.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Oral medicin department, "Shahid Beheshti dental faculty", Tehran, Iran

Full name of responsible person

Nasrin Rafieian, Resident

Street address

Shahid Beheshti University, Daneshjoo BUL, Evin

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Vahideh Dastjerdi

Street address

University of Medical Sciences

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

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Full name of responsible person

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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