Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the efficacy of Triamcinolone Acetonide 0.1 % in Orabase with it's nanoliposomal carriers formulation on oral Lichen Planus patients

Protocol summary

Summary

In this study we decided to compare the anti-inflammatory effects of Triamcinolone Acetonide 0.1% with nanoliposomal carriers formulation in Orabase and the common formulation of Triamcinolone Acetonide 0.1% in Orabase on referral patients with oral Lichen Planus to Oral Medicine Department of Dental Branch, Islamic Azad University of Tehran in 2013-2014. This study is performing in the manner of double blind (for investigators and patients) randomized clinical trial and in a single center on 40 patients with erythematous-ulcerative oral Lichen Planus. Inclusion criteria are all patients with symptomatic oral lesions suspected of Lichen Planus; with clinical and histological diagnosis of atrophic or erosive oral Lichen Planus and Exclusion criteria are presence of dysplasia on histological examination; pregnancy; nursing; dysfunction of immune system; hematologic diseases; systemic diseases; history of systemic or topical corticosteroid therapy for Lichen Planus in the past month; Lichenoid reactions due to drug use or restorative materials. Triamcinolone Acetonide 0.1% with nanoliposomal carriers in orabase and Triamcinolone Acetonide 0.1% in orabase are using 3 times a day for a month in case and control groups, respectively. Pain intensity by Linear Visual Analogue Scale (0-10) and area of the erythematous-ulcerative lesions by grid (mm2) are recording before, one, two and four weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080416090N5**
Registration date: **2014-10-04, 1393/07/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-10-04, 1393/07/12

Registrant information

Name

Arash Azizi

Name of organization / entity

Islamic Azad university-Dental Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 0925

Email address

a_azizi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Dental Branch, Islamic Azad University of Tehran

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of Triamcinolone Acetonide 0.1 % in Orabase with it's nanoliposomal carriers formulation on oral Lichen Planus patients

Public title

Comparison the efficacy of Triamcinolone Acetonide 0.1 % in Orabase with it's nanoliposomal carriers formulation on oral Lichen Planus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: All referral patients to Oral Medicine Department of Dental Branch, Islamic Azad University of Tehran with symptomatic oral lesions suspected of Lichen Planus; with confirmed diagnosis clinically and histologically of atrophic or erosive oral Lichen Planus. Exclusion Criteria: presence of dysplasia on histological examination; pregnancy; nursing; dysfunction of immune system(organ transplantation, lupus erythematous, ulcerative colitis); hematologic diseases; systemic diseases; history of systemic or topical corticosteroid therapy for Lichen Planus in the past month; Lichenoid reactions due to drug use or restorative materials.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dental Branch, Islamic Azad University of Tehran

Street address

No. 4, 10th Neyestan, Pasdaran St.

City

Tehran

Postal code

Approval date

2010-09-24, 1389/07/02

Ethics committee reference number

د/214/پ

Health conditions studied

1

Description of health condition studied

Lichen Planus

ICD-10 code

L43

ICD-10 code description

Papulosquamous disorders

Primary outcomes

1

Description

pain intensity

Timepoint

before treatment, 1, 2 and 4 weeks after treatment

Method of measurement

Visual Analogue Scale

2

Description

area of the erythematous-erosive lesion

Timepoint

before treatment, 1, 2 and 4 weeks after treatment

Method of measurement

mm2

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Triamcinolone Acetonide 0.1% with nanoliposomal carriers in Orabase, Oral paste, three times a day for a month

Category

Treatment - Drugs

2

Description

Control group: Triamcinolone Acetonide 0.1% in Orabase, Oral paste, three times a day for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Branch Islamic Azad University of Tehran

Full name of responsible person

Dr. Arash Azizi
Street address
No. 4, 10th Neyestan, Pasdaran St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental Branch Islamic Azad University of Tehran
Full name of responsible person
Dr Rima Hossein Zade Nik
Street address
No. 4, 10th Neyestan, Pasdaran St.
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dental Branch Islamic Azad University of Tehran
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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Person responsible for scientific inquiries

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Person responsible for updating data

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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