

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 (mm<sup>2</sup>) 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 erythematosus, 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**

mm<sup>2</sup>

### **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.

**City**

Tehran

## 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.

**City**

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**

Dental Branch Islamic Azad University of Tehran

**Full name of responsible person**

Dr. Arash Azizi

**Position**

Oral Medicine Specialist

**Other areas of specialty/work**

**Street address**

Oral Medicine Department, No. 4, 10th Neyestan, Pasdaran St.

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**Phone**

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Dental Branch Islamic Azad University of Tehran

**Full name of responsible person**

Dr. Arash Azizi

**Position**

Associate

**Other areas of specialty/work**

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## Person responsible for updating data

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Dental Branch Islamic Azad University of Tehran

**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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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*