

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Comparison of the effect of Infra- red low level laser 810 nm with Triamcinolone 0.2 % mouthwash in treatment of Oral Lichen Planus lesions

#### Protocol summary

##### Summary

Oral lichen Planus causes pain and affected the nutrition and quality of life of the patients. Due to the high prevalence of disease , common side effects, and resistance to classic drug treatment , in this research we compared the effect of Infra rad low level laser 810 nm with Triamcinolone acetone 0/2% mouthwash (classic treatment for OLP). In this randomized controlled clinical trial study 24 patients were selected based on included and excluded criteria(inclusion:patients with diagnose of OLP,patients agree to this RCT and exclusion criteria :receive any corticosteroids drug in recent two month, being in pregnancy or breast feeding period , patient with systemic disorder , lesion with dysplasia ,drug induced lichenoid reaction) , which were divided in two groups of 12 people according to sequential randomized sampling .before starting this research the indicators such as pain (VAS), score and size of the lesion were recorded. The first group were treated by infra red diode laser twice a week with 0/5-2 J/cm2 power density and 300 mW output power up to 10 sessions. The second group were taken Triamcinolone acetone 0/2% mouthwash for four times daily with anti fungal drugs for a month

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016042027501N1**

Registration date: **2017-06-01, 1396/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-01, 1396/03/11

#### Registrant information

##### Name

Mandana Khatibi

##### Name of organization / entity

Tehran Azad University faculty of Dentistry

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 4571

##### Email address

m\_khatibi@dentaliau.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Personal

#### Expected recruitment start date

2016-05-04, 1395/02/15

#### Expected recruitment end date

2017-03-19, 1395/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of Infra- red low level laser 810 nm with Triamcinolone 0.2 % mouthwash in treatment of Oral Lichen Planus lesions

#### Public title

Comparison of the effect of Infra- red low level laser 810 nm with Triamcinolone 0.2 % mouthwash in treatment of Oral Lichen Planus lesions

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion:patients with diagnose of OLP,patients agree to this RCT exclusion :receive any corticosteroids drug in recent two month, being in pregnancy or breast feeding period , patient with systemic disorder , lesion with dysplasia ,drug induced lichenoid reaction

#### Age

From **30 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **24**

#### 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 Tehran Azad University Faculty of Dentistry

##### Street address

Tehran Azad University faculty of Dentistry, 10th Neyestan St, Pasdaran Ave, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2016-04-09, 1395/01/21

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1395,42

## Health conditions studied

### 1

#### Description of health condition studied

Oral Lichen Planus

#### ICD-10 code

L43

#### ICD-10 code description

Lichen planus

## Primary outcomes

### 1

#### Description

Pain and Soreness

#### Timepoint

Before and after treatment and in follow up

#### Method of measurement

Asking from patients

### 2

#### Description

Size of lesion

#### Timepoint

Before and after treatment

#### Method of measurement

Oral Probe

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

12 patients were treated by infra red diode laser twice a week with 0/5-2 J/cm2 power density and 300 mW output power up to 10 sessions.

#### Category

Treatment - Other

### 2

#### Description

12 patients in control group will be treated with Triamcinolone acetone 0.2% and anti fungal( Nystatin ) Tid for 4 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tehran Azad University Faculty of Dentistry, Oral Medicine Department

##### Full name of responsible person

Dr Soheila Mohamadian

##### Street address

Tehran Azad University Faculty of Dentistry, 10th Neyestan St, Pasdaran Ave, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Private

**Full name of responsible person**

Dr Soheila Mohamadian

**Street address**

Tehran Azad University faculty of Dentistry, 10th  
Neyestan St, Pasdaran Ave, Tehran, Iran

**City**

Tehran

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

Yes

**Title of funding source**

Private

**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**

Tehran Azad University faculty of Dentistry

**Full name of responsible person**

Dr Soheila Mohamadian

**Position**

Resident of Oral Medicine

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate Professor

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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