

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparative evaluation of low-power laser and co2 laser in treatment of patients with oral lichen planus presenting to the oral Medicine Department at the Dentistry faculty in Tehran University of Medical Sciences in 1388-1389.

#### Protocol summary

##### Summary

The aim of this study is to compare the effects of low-power laser and co2 laser on decreasing sign and symptom of oral lichen-planus lesions. It is an open-labeled, before-after study, treating 60 lesions (30 lesions in low-power laser group and 30 lesions in co2 laser group) with clinical and histopathologic diagnosis of lichen-planus. The participants are recruited among the patients who refer to the Oral Medicine Department at the Dentistry Faculty in Tehran University of Medical Sciences (TUMS). The lesions in low-power laser group receive first, visible red laser light then, infra-red laser light every other day for 5 sessions. The lesions in co2 laser group receive laser light at one session and follow-up sessions are the same as low- power laser group. Before treatment and during these sessions the patients will ne asked for pain and burning sensation. The size of lesions is also assessed with scaled tongue blade. The scores of the lesions are recorded each time, based on thongprasom sigh scoring by the researcher. Pain and burning sensation are measured by using visual analogue scale. The patients are examined at the baseline and 2 and 4 weeks and also 2 and 3 months after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008161559N4**  
Registration date: **2010-09-12, 1389/06/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-09-12, 1389/06/21

##### Registrant information

###### Name

Farzaneh Aghahoseini

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6611 2437

###### Email address

aghahose@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2009-04-04, 1388/01/15

##### Expected recruitment end date

2010-10-07, 1389/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of low-power laser and co2 laser in treatment of patients with oral lichen planus presenting to the oral Medicine Department at the Dentistry faculty in Tehran University of Medical Sciences in 1388-1389.

##### Public title

Comparative evaluation of low-power laser and co2 laser in treatment of oral lichen planus.

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: clinical and histopathologic diagnosis of lichen planus with clinical criteria, consisting of the presence of symmetric reticular or papular lesions with or without erosive-atrophic components. Histopathologic features of oral lichen planus are: 1) Areas of hyperparakeratosis or hyperorthokeratosis, often with a thickening of the granular cell layer and a saw-toothed appearance to the retepages. 2) Liquefaction degeneration or necrosis of the basal layer. 3) A dense subepithelial band, shaped by infiltration of lymphocytes T and macrophages. 4) Absence of dysplastic changes. Exclusion criteria: Using drugs (including for the treatment of lichen planus at the first session) and exposure to amalgam fillings.

### **Age**

No age limit

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 60

### **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**

Dental Sciences Research center, Tehran University of Medical Sciences

##### **Street address**

Dental Sciences Research center, Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2010-05-25, 1389/03/04

### **Ethics committee reference number**

890170-10045

## **Health conditions studied**

### 1

#### **Description of health condition studied**

lichen planus

#### **ICD-10 code**

L43

#### **ICD-10 code description**

lichen planus

## **Primary outcomes**

### 1

#### **Description**

size of lesions

#### **Timepoint**

2 weekly in the first month and then monthly for 3 months

#### **Method of measurement**

size of lesions with scaled tongue blade

### 2

#### **Description**

pain and discomfort in the oral lesions

#### **Timepoint**

2 weekly in the first month and then monthly for 3 months

#### **Method of measurement**

VAS

### 3

#### **Description**

clinical score

#### **Timepoint**

2 weekly in the first month and then monthly for 3 month

#### **Method of measurement**

Registration the primary scores of lesions and their changes on the follow up period as described in the material and method

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Low power laser including red light ( $\lambda=633$  nm, light exposure dose=0.3 J/cm<sup>2</sup>) and infrared light ( $\lambda=830$  nm, light exposure dose=0.3 J/cm<sup>2</sup>) every other day for 5 sessions

#### **Category**

Treatment - Other

## 2

### Description

Co2 laser ( $\lambda=10600$  nm, 20 W) at one session.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Oral medicine department of Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Aghahosseini , Dr. Elham Moslemi

##### Street address

Oral medicine department, Dentistry faculty, Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research center of dental Science of Tehran University of medical sciences

##### Full name of responsible person

Dr. Azam khorshidian

##### Street address

Dental Sciences Research center, Tehran University of Medical Sciences

##### City

Tehran

#### Grant name

در اختیار دانشگاه علوم پزشکی تهران

#### Grant code / Reference number

Tehran University of Medical Sciences

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Research center of dental Science of 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

Oral Medicine Department, Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Elham Moslemi

#### Position

Resident of oral medicine

#### Other areas of specialty/work

#### Street address

Oral medicine department of Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

#### City

Tehran

#### Postal code

#### Phone

+98 21 8838 4235

#### Fax

#### Email

dr.emoslemi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Oral medicine department of Tehran University of Medical Sciences

#### Full name of responsible person

Dr Farzaneh Aghahoseini

#### Position

Professor

#### Other areas of specialty/work

#### Street address

Oral medicine department, Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, Iran

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#### Phone

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#### Email

aghahose@ sina.tums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

## 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*