

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### evaluation the effect of low level and high level laser therapy on recurrent aphthous stomatitis and comparison of their effects together

#### Protocol summary

##### Summary

There are limited number of studies about the laser effect on aphthous ulcers,so we want to assess the effect of low and high level laser therapy on the severity of pain, pain duration and the duration of tissue repair in aphthous ulcers. In this study 30 patients with at least 1 minor aphthous stomatitis not longer than 72 hours from their incidence will be evaluated. Pregnant and breast feeder women, patients with severe heart, liver and renal problems, patients undergone local and systemic therapy with corticosteroids and antibiotics in the previous month will be excluded. Patients will be divided into 3 groups randomly. one group will be treated with low level laser(4min, 25mW, 670nm, Azor laser), the second group with high level laser(10-5s, 2W,10600nm, CO2laser) and the last one with the laser hand-piece on the off mode as the placebo treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012120911702N1**

Registration date: **2013-02-04, 1391/11/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-02-04, 1391/11/16

##### Registrant information

###### Name

Nasim Zeini Jahromi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1630 4539

##### Email address

zeinin@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

evaluation the effect of low level and high level laser therapy on recurrent aphthous stomatitis and comparison of their effects together

##### Public title

evaluation of laser effect on recurrent aphthous ulcers

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with at least 1 minor aphthous stomatitis; not longer than 72 hours from the incidence of the lesion Exclusion criteria: Pregnant and breast feeder women; patients with severe heart, liver and renal problems; patients undergone local and systemic therapy with corticosteroids and antibiotics in the previous month

##### Age

No age limit

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 30

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Zand street

##### City

Shiraz

##### Postal code

#### Approval date

2012-09-13, 1391/06/23

#### Ethics committee reference number

CT-91-4105

## Health conditions studied

### 1

#### Description of health condition studied

recurrent aphthous stomatitis

#### ICD-10 code

k12.0

#### ICD-10 code description

K12.0 Recurrent oral aphthae

## Primary outcomes

### 1

#### Description

severity of pain

#### Timepoint

every day up to 10 days

#### Method of measurement

visual analogue scale

## Secondary outcomes

### 1

#### Description

duration of ulcers

#### Timepoint

every day up to 10 days

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

low level laser therapy: Azor laser, 670nm, 25mW, 4min

#### Category

Treatment - Other

### 2

#### Description

high level laser therapy: CO2 laser, 10600nm, 2W, 5-10s

#### Category

Treatment - Other

### 3

#### Description

placebo treatment: the low level laser hand-piece on the off mode, 4min

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz Dental School

##### Full name of responsible person

Nasim Zeini Jahromi

##### Street address

Ghasrodasht

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Pustforosh

##### Street address

Zand st.

##### City

Shiraz

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Nasim Zeini Jahromi  
**Position**  
student  
**Other areas of specialty/work**  
**Street address**  
Shiraz Dental School  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 1628 9917  
**Fax**  
**Email**  
nasim.zeini@yahoo.comnasim.zeini.85@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Shiraz Dental School  
**Full name of responsible person**  
Nasim Zeini Jahromi  
**Position**  
post graduate student

**Other areas of specialty/work**  
**Street address**  
Ghasrodasht  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 1628 9917  
**Fax**  
**Email**  
nasim.zeini@yahoo.com  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shiraz Dental School  
**Full name of responsible person**  
Nasim Zeini Jahromi  
**Position**  
student  
**Other areas of specialty/work**  
**Street address**  
Ghasrodasht  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 1628 9917  
**Fax**  
**Email**  
nasim.zeini@yahoo.comnasim.zeini.85@yahoo.com  
**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*