

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

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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

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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