

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of Low Level Laser Therapy (660 nm) and Methylene Blue-mediated Photodynamic Therapy with laser (660 nm) in patient with oral ulcerative and erythematous Lichenoid Reaction

Protocol summary

Study aim

Comparison of the effect of Low Level Laser Therapy(660 nm) and methylene blue-mediated Photodynamic Therapy with Laser (660 nm) in patient with oral ulcerative and erythematous Lichenoid Reaction

Design

clinical trial, parallel groups, single-blind, non-randomized, 10 patients.

Settings and conduct

This study will be conducted with the consent and knowledge of eligible patients in the dental clinic of Esfahan Azad University. This study is single blinded. The examiner of oral lesion will not be aware of which treatment method is applied on each side of the mouth. The characteristics of the lesion (pain, burning sense and size of the lesion) are recorded on both sides of the mouth. on one side. low level laser therapy(660 nm) is used. and on the other side ,methylene blue is first used on lesions ,and then 10 minutes later, low level laser therapy(660 nm) is applied. This process is done twice a week for two weeks and one month follow up. pain, duration of clinical recovery of red or ulcerative areas, duration of pain relief and dimensional changes of lesions will be examined.

Participants/Inclusion and exclusion criteria

Clinical diagnosis and pathology of the disease; absence of dysplastic changes in pathology report , patient consent; erythematous and ulcerative (erosive) types of lesion

Intervention groups

In eligible participants, on one side of oral cavity , low level laser therapy(660 nm) is used , and on the other side ,methylene blue is first used on lesions ,and then low level laser therapy(660 nm) is applied.

Main outcome variables

Recovery time(The number of days) dimensional changes of erythematous and ulcerative lesions(in mm²)

Reducing the burning sense of erythematous and ulcerative lesions (VAS) duration of pain relief erythematous and ulcerative lesions(The number of days)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230522058261N1**

Registration date: **2023-12-18, 1402/09/27**

Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**

Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Reyhane Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3633 6580

Email address

rey.rezaei@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-19, 1402/09/28

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Low Level Laser Therapy (660 nm) and Methylene Blue-mediated Photodynamic Therapy with laser (660 nm) in patient with oral ulcerative and erythematous Lichenoid Reaction

Public title
Comparison of the effect of Low Level Laser Therapy and methylene blue-mediated Photodynamic Therapy with Laser in patient with oral ulcerative and erythematous lichenoid reaction.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Clinical diagnosis and pathology of oral Lichen Planus or Lichenoid drug eruption Erythematous and ulcerative types (erosive) Patient consent
Exclusion criteria:
 Dysplasia changes in pathology report Lack of patient consent

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **10**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 on one side of oral cavity , low level laser therapy(660 nm) is used , and on the other side ,methylene blue is first used on lesions ,and then low level laser therapy(660 nm) is applied.

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The researcher who will apply treatment methods on oral lesion will be different from a person who examine the outcome of treatment methods. The examiner of oral lesion will not be aware of which treatment method is applied on each side of the mouth

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University - Esfahan Branch (Khorasgan)

Street address

Dentistry Faculty .,Esfahan Azad University., University Street., Arghavanieh Blvd.,

City

Esfahan

Province

Isfahan

Postal code

81551-39998

Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.IAU.KHUISF.REC.1402.090

Health conditions studied

1

Description of health condition studied

Erythematous and ulcerative Oral Lichenoid

ICD-10 code

L43

ICD-10 code description

Lichen planus

Primary outcomes

1

Description

Pain

Timepoint

Twice a week

Method of measurement

VAS

2

Description

duration of pain relief erythematous and ulcerative lesions

Timepoint

Each treatment session and follow-up.

Method of measurement

Based on the number of days

3

Description

dimensional changes of the lesion

Timepoint

Twice a week

Method of measurement

Square millimeters

4**Description**

Recovery time

Timepoint

Checking during treatment sessions and follow-up

Method of measurement

Number of days

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: This group will include patients that laser 660 nm will be applied on the left side of their mouth.

Category

Treatment - Other

2**Description**

Intervention group: On the right side of the same patients, we will first use methylene blue (MB) with a concentration of 0.05 gr per 100 cc for 10 minutes and then 660 nm laser will be applied.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental Faculty

Full name of responsible person

Amir Mansour Shirani

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Dentistry Faculty .,Esfahan Azad University.,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address

https://isfahan.iau.ir/dental/fa

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Amir Mansour Shirani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In cases that can be done legally and ethically.

When the data will become available and for how long

The period of access to this information will start on 03-18-2024.

To whom data/document is available

Authorized persons in the study

Under which criteria data/document could be used

If needed, it will be given to a competent officer.

From where data/document is obtainable

Researcher

What processes are involved for a request to access data/document

Letter to the university

Comments