

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparing the efficacy of photodynamic laser 660 by methylene blue with photodynamic laser 810 by indocyanine green on denture stomatitis

#### Protocol summary

##### Study aim

Comparing the efficacy of photodynamic laser 660 by methylene blue with photodynamic laser 810 by indocyanine green on denture stomatitis

##### Design

This is a randomized, double-blinded clinical trial with a parallel design. Phase 2-3 this randomized study will be conducted on 40 patients with dentures. A blocking random method is used for randomization and the participants are assigned to two intervention groups.

##### Settings and conduct

This study, which will be conducted in the Faculty of Dentistry of Isfahan Azad University, is a double-blinded one. The researcher and the participants have no role in allocating intervention and control groups. The same researcher evaluates the presence or absence of denture stomatitis based on clinical symptoms and direct observations of the palate mucosa, which is classified into three types according to Newton's suggestion.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Patients with dentures and confirmed clinical evidence of denture stomatitis  
Exclusion criteria: Patients with a history of diabetes, immunosuppression, radiotherapy, and chemotherapy; Patients who have received antibiotics, antifungal drugs, or steroids in the last 3 months

##### Intervention groups

In the first intervention group, photodynamics will be sprayed by means of methylene blue with laser 660 twice a week for two weeks, on both the surface of the prosthesis and the palatal mucosa with light-sensitive methylene blue with a concentration of 450 µg/ml for 10 minutes before the irradiation. In the second intervention group, photodynamics by green indocyanine with laser 810, twice a week for two weeks with a concentration of 1 mg/ml in sterile distilled water will be prepared and kept at room temperature until use..

##### Main outcome variables

The extent of red, burning areas

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N203**

Registration date: **2023-07-18, 1402/04/27**

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

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

##### Registration date

2023-07-18, 1402/04/27

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-11, 1402/04/20

##### Expected recruitment end date

2023-10-12, 1402/07/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing the efficacy of photodynamic laser 660 by methylene blue with photodynamic laser 810 by indocyanine green on denture stomatitis

## Public title

Comparing the efficacy of photodynamic laser 660 by methylene blue with photodynamic laser 810 by indocyanine green on denture stomatitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Informed consent Patients with dentures and confirmed clinical evidence of denture stomatitis

### Exclusion criteria:

Patients with a history of diabetes, immunosuppression, radiotherapy, and chemotherapy Patients who have received antibiotics, antifungal drugs or steroids in the last 3 months

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site <https://www.sealedenvelope.com> is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Medications can only be identified by the serial number on the container. The serials are with the main doctor and will remain confidential until the end of the study. The charge of injecting medications will not know about the assignment of individuals to groups. The participants will not know about the allocation of study groups. Therefore, this study will be a double-blinded one

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan Branch (Khorasgan), Ethics Committee of Islamic Azad University

##### Street address

Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8155139998

#### Approval date

2023-01-07, 1401/10/17

#### Ethics committee reference number

IR.IAU.KHUISF.REC.1401.330

## Health conditions studied

### 1

#### Description of health condition studied

Denture Stomatitis

#### ICD-10 code

K12.1

#### ICD-10 code description

Other forms of stomatitis

## Primary outcomes

### 1

#### Description

The extent of red

#### Timepoint

The beginning of the study and the end of the study (two weeks later)

#### Method of measurement

Using Visual Analogue Scale

### 2

#### Description

Burning areas

#### Timepoint

The beginning of the study and the end of the study (two weeks later)

#### Method of measurement

Using Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the first intervention group, photodynamics will be sprayed by means of methylene blue with laser 660 twice a week for two weeks, on both the surface of the prosthesis and the palatal mucosa with light-sensitive methylene blue with a concentration of 450 µg/ml for 10 minutes before the irradiation.

#### Category

Treatment - Drugs

### 2

#### Description

In the second intervention group, photodynamics with laser 810 twice a week by green indocyanine will be prepared for two weeks with a concentration of 1 mg/ml in sterile distilled water and kept at room temperature until use. It should be applied on both the prosthesis and the palate mucosa surfaces with a sterile water swab. After 10 minutes, laser irradiation is performed by an experienced operator using an 810 nm diode laser.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry, Azad University, Khorasgan branch

##### Full name of responsible person

Mahsa Khodadadian

##### Street address

Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8155139998

##### Phone

+98 31 3535 4001

##### Email

mahsakh3076@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University faculty member

##### Full name of responsible person

Dr. Majid Meshkini

##### Street address

Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

##### City

Isfahan

##### Province

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##### Postal code

8155139998

##### Phone

+98 31 3535 4001

##### Email

meshkini@miums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

University faculty member

#### Proportion provided by this source

100

#### Public or private sector

Public

#### 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, Khorasgan branch

##### Full name of responsible person

Mahsa Khodadadian

##### Position

Student of dental

##### Latest degree

A Level or less

##### Other areas of specialty/work

Dentistry

##### Street address

Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

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mahsakh3076@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Dr. Amir Mansour Shirani

**Position**

University faculty member

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Mahsa Khodadadian

**Position**

Student of dental

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

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+98 31 3535 4003

**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available