

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effectiveness of photodynamics with laser810 by Indocyanine green with miconazole on denture stomatitis

#### Protocol summary

##### Study aim

Comparing the effectiveness of photodynamics with laser 810 by Indocyanine green with miconazole on denture stomatitis

##### Design

This is a randomized, double-blinded clinical trial with a parallel design and a control group. Phase 2-3 this randomized study will be conducted on 40 patients with dentures. A simple 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, in addition to miconazole 2% gel that they receive 4 times a day for two weeks, Photodynamics is prepared with light-sensitive green indocyanine at a concentration of 1 mg/ml in sterile distilled water and will be stored in a dark place at room temperature until use. After 10 minutes laser irradiation is performed by an experienced operator using an 810 nm diode laser. The second intervention group will receive miconazole 2% gel 4 times a day for two weeks. For each use, 2.5 ml of gel is applied to the artificial tooth, which is immediately placed in.

#### Main outcome variables

fungal infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N201**

Registration date: **2023-06-06, 1402/03/16**

Registration timing: **prospective**

Last update: **2023-06-06, 1402/03/16**

Update count: **0**

##### Registration date

2023-06-06, 1402/03/16

##### 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

2023-06-10, 1402/03/20

##### Expected recruitment end date

2023-09-11, 1402/06/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparing the effectiveness of photodynamics with laser810 by Indocyanine green with miconazole on denture stomatitis

**Public title**  
Comparing the effectiveness of photodynamics with laser 810 by Indocyanine green with miconazole 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**

- Participant
- Investigator

**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**  
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.1401.331

## 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**  
fungal infection

**Timepoint**  
The beginning and end of the study

**Method of measurement**  
Examination and observation of the dentist

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

In the first intervention group, in addition to miconazole 2% gel that they receive 4 times a day for two weeks, Photodynamics is prepared with light-sensitive green indocyanine at a concentration of 1 mg/ml in sterile distilled water and will be stored in a dark place at room temperature until use. Then it is placed on the lesion of the palate with a sterile swab, after 10 minutes laser irradiation is performed by an experienced operator using an 810 nm diode laser.

### Category

Treatment - Other

## 2

### Description

The second intervention group will receive miconazole 2% gel 4 times a day for two weeks (with a cotton swab placed on the inner surface of the artificial tooth). For each use, 2.5 ml of gel is applied to the artificial tooth, which is immediately placed in.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry, Azad University, Khorasgan branch

##### Full name of responsible person

Zahra 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

zakhma3008@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

Isfahan

##### 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

Zahra Hadadian

##### 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

##### City

Isfahan

##### Province

Kermanshah

##### Postal code

8155139998

##### Phone

+98 31 3535 4003

##### Email

zakhma3008@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**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

۷۱۹۳۶۱۳۳۱۱

**Phone**

+98 31 3535 4003

**Email**

amir.mansour.shirani@gmail.com

**Other areas of specialty/work**

Dentistry

**Street address**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8155139998

**Phone**

+98 31 3535 4003

**Email**

zakhma3008@gmail.com

**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

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

Islamic Azad University, Khorasgan branch

**Full name of responsible person**

Zahra Hadadian

**Position**

Student of dental

**Latest degree**

A Level or less