

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University faculty member

Full name of responsible person

Dr. Majid Meshkini

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

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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

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

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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

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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

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