Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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)

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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
Isfehan

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
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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
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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
Mahsa Khodadadian
Position
Student of dental
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Amir Mansour Shirani
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Person responsible for updating data

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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