Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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
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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

Isfehan

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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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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Contact

Name of organization / entity
Islamic Azad University, Khorasgan branch

Full name of responsible person
Dr. Amir Mansour Shirani
Position
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Latest degree
Specialist
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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