

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Evaluation of Indocyanine green mediated photodynamic therapy on grade and size of Denture stomatitis

#### Protocol summary

##### Study aim

Evaluation of the lesion size and candida colony count before and after photodynamic therapy and treatment with nystatin and comparing them.

##### Design

This is a parallel, double blind randomized clinical trial (phase 2) with control group on twenty four patients in each group who will be enrolled randomly by block randomization.

##### Settings and conduct

Participants with denture stomatitis attending at Shiraz University of Dental School will be enrolled in this study. In intervention group nystatin therapy and photodynamic therapy will be considered. In control group just nystatin therapy will be prescribed. Their effect will be compared. Since patients do not know the on or off mode of laser and also the outcome assessor will not know type of treatment, both will be blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : patient with denture stomatitis  
exclusion criteria: diabetic patient, patient who used antibiotic or anti fungal or corticosteroids within last 3 months, immune suppressed patients.

##### Intervention groups

Intervention group: Patient with denture stomatitis will be treated by nystatin solution (Jaber-ebn-Haian company, Tehran, Iran). Lesion will be applied by indocyanin green (Ench industry company, Shandong, China). A diode laser (A.R.C. laser GmbH, Nurnberg, Germany) with wavelength of 810 nm with 300 mW, continuous mode, 30 seconds and resultant energy density of 55J/cm<sup>2</sup> and spot size of 4.5mm will be used for activation of this dye. Photodynamic therapy will be done in day 1 and day 15. Control group: Patient with denture stomatitis will be treated by nystatin solution. Lesion will be applied by indocyanin green. Sham laser will be used.

##### Main outcome variables

lesion size, colony count

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120101008585N6**

Registration date: **2018-12-26, 1397/10/05**

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

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

##### Registration date

2018-12-26, 1397/10/05

##### Registrant information

##### Name

Fatemeh Lavaee

##### Name of organization / entity

Shiraz Dental School

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1631 9309

##### Email address

lavaeef@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-02, 1397/05/11

##### Expected recruitment end date

2019-08-02, 1398/05/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of Indocyanine green mediated photodynamic therapy on grade and size of Denture stomatitis

## Public title

Effect of indocyanin green on denture stomatitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Edentulous denture-wearing patients with denture stomatitis

### Exclusion criteria:

Immunosuppressive patient Diabetic patient Patient who used antibiotic, antifungal medication or corticosteroid during last 3 months Chemotherapy or radiotherapy

## Age

From **20 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 48 participants (12 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 48 cards a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participant will be blind to their treatment. Nystatin oral suspension will be prescribed in both groups. In the intervention group photodynamic therapy will be done at the same period. In the control group sham laser will be irradiated. Since patients do not know the on or off mode of applied laser and also since the assessor of parameters is different from the one who will apply laser, both participants in intervention group and the assessor will be blind.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Namazi square, Zand street, Shiraz, Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

7186781559

#### Approval date

2018-07-29, 1397/05/07

#### Ethics committee reference number

ir.sums.rec.1397.411

## Health conditions studied

### 1

#### Description of health condition studied

Denture stomatitis

#### ICD-10 code

B37.0

#### ICD-10 code description

Candidal stomatitis

## Primary outcomes

### 1

#### Description

Lesion size

#### Timepoint

Day 1 and 15

#### Method of measurement

Newton's classification

### 2

#### Description

candida colony count

#### Timepoint

Day 1 and 15

#### Method of measurement

CFU/ml colony count

## Secondary outcomes

### 1

#### Description

Indocyanine green hypersensitivity

**Timepoint**

Day 1 and 15

**Method of measurement**

clinical symptom of hypersensitivity

**Intervention groups****1****Description**

Intervention group: Nystatin oral suspension (100 000 U manufactured by Jaber-ebn-Haian) will be prescribed to swish it for 4 min, gargle, and then expectorate it three times daily for 15 days. Photodynamic therapy will be applied on denture stomatitis lesions in day 1 and 15. Topical indocyanin green (Ench industry company, Shandong, China) will be applied with micropipette on lesion and after 10 min, the lesion will be irradiated with a 810nm diode laser for 30sec (power: 300mW).

**Category**

Treatment - Other

**2****Description**

Control group: nystatin oral suspension (100 000 U manufactured by Jaber-ebn-Haian company) will be prescribe to swish it for 4 min, gargle, and then expectorate it three times daily for 15 days. Topical indocyanin green (Ench industry company, Shandong, China) with micro pipette and sham laser irradiation will done in day 1 and 15.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

School of Dentistry, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr.Fateme Lavaee

**Street address**

Shiraz Dental School, Ghasrdasht street, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7186781559

**Phone**

+98 71 3628 0456

**Fax**

+98 71 3626 3193

**Email**

dental@sums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Basir Hashemi

**Street address**

Shiraz university of Medical Sciences, Zand street, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7186782559

**Phone**

+98 71 3212 2438

**Email**

hashemib@sums.ac.ir

**Web page address****Grant name****Grant code / Reference number**

95-01-03-11515

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Lavaee

**Position**

Assistant Professor of Oral and Maxillofacial Medicine Department

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

**City**

shiraz

**Province**  
Fars  
**Postal code**  
7186781559  
**Phone**  
+98 71 3631 9309  
**Email**  
lavaeef@sums.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Lavaee  
**Position**  
Assistant Professor of Oral and Maxillofacial Medicine  
Department  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shiraz School of Dentistry, Ghasrdasht street, Shiraz,  
Iran  
**City**  
shiraz  
**Province**  
Fars  
**Postal code**  
7186781559  
**Phone**  
+98 71 3631 9309  
**Email**  
lavaeef@sums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Lavaee  
**Position**  
Assistant Professor of Oral and Maxillofacial Medicine  
Department  
**Latest degree**

Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shiraz School of Dentistry, Ghasrdasht street, Shiraz,  
Iran  
**City**  
shiraz  
**Province**  
Fars  
**Postal code**  
7186781559  
**Phone**  
+98 71 3631 9309  
**Email**  
lavaeef@sums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All collected data will be shared after deidentification of participants.

### When the data will become available and for how long

6 months after publication data will become available.

### To whom data/document is available

The researchers in academic institutions.

### Under which criteria data/document could be used

The researchers in academic institutions.

### From where data/document is obtainable

The researchers in academic institutions can email responsible person and request information.

### What processes are involved for a request to access data/document

The researchers in academic institutions can email responsible person and request information.

### Comments