# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The effect of Indocyanine green mediated photodynamic therapy in combination with low level laser therapy on pain and size of chemotherapy induced oral mucositis

## Protocol summary

**Study aim**

Determination the effect of indocyanine green mediated photo dynamic therapy in combination with laser therapy on chemotherapy induced oral mucositis

**Design**

In this randomized, blinded, clinical trial, Patients with oral mucositis will be enrolled in two groups by block randomization. In intervention group 20 patients will receive photodynamic therapy from emerging the first manifestation of oral mucositis induced by chemotherapy, once a week for 4 weeks. In control group 20 patients will receive the sham laser. The pain and size of the lesions will be evaluated according to WHO and NCI scores.This study is the third phase of clinical trial.

**Settings and conduct**

This randomized clinical study will be done on 40 patients with acute leukemia who are admitted in Namazee and Amir hospitals and are under chemotherapy during 2022-2023.The investigator who evaluate the pain and size of lesions, and the data analyzer are blind to the type of treatment.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: patients above 8 years old with chemotherapy induced oral mucositis who sign the consent form will be included. Exclusion criteria: patients under chemotherapy for any reason except acute leukemia, allergic to the Indocyanine green stain, having diabetes mellitus, and refuse to sign the consent form will be excluded.

**Intervention groups**

Photodynamic therapy will be started from emerging the first manifestation of oral mucositis induced by chemotherapy, once a week for 4 weeks. indocyanine green will be used for photodynamic therapy and low level laser will be applied for activation of this vital stain. after dilution of indocyanine green (0.1 mg/ml) the patients will gargle it and after 10 minutes, a low level laser with wave length of 808 nm and a dose 50 J/cm² will be radiated on an oral lesion on non-keratinized mucosa of participants.

**Main outcome variables**

Pain; size

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20120101008585N16**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**
Update count: **0**

**Registration date**

2022-12-04, 1401/09/13

**Registrant information**

**Name**
Fatemeh Lavaee
**Name of organization / entity**
Shiraz Dental School
**Country**
Iran (Islamic Republic of)
**Phone**
+98 71 1631 9309
**Email address**
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-12-21, 1401/09/30

**Expected recruitment end date**

2023-12-21, 1402/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Indocyanine green mediated photodynamic therapy in combination with low level laser therapy on pain and size of chemotherapy induced oral mucositis

**Public title**

The effect of photodynamic therapy on oral mucositis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients above 8 years old Patients with intact mucosa at the beginning of the study Patients with chemotherapy induced oral mucositis Patients signing the consent form

**Exclusion criteria:**

Patients under chemotherapy for any reason except acute leukemia Patient who are allergic to the Indocyanine green stain Patients with diabetes mellitus Patients refusing to sign the consent form

**Age**

From **8 years** old to **99 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each block with 4 allocations, consisting of 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 40 participants (10 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 40 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 the order of enrollment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

One of the researchers will prescribe the treatment and another researcher will assess the outcome. Therefore, the researchers will be blind. The statistical analyzer will be blind to the type of treatment in each group. The outcome assessor, patients and statistical analyzer will be blind to the prescribed treatment. Both groups of patients will receive chlorhexidine and nystatin as routine treatment. The patients in the intervention group will receive low level laser, but the patients in control group will receive sham laser.

**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 Science, Zand street, Shiraz, Fars

**City**

Shiraz

**Province**

Fars

**Postal code**

1433671348

**Approval date**

2022-09-12, 1401/06/21

**Ethics committee reference number**

1401.480.IR.SUMS.REC

## Health conditions studied

### 1

**Description of health condition studied**

Chemotherapy induced oral mucositis

**ICD-10 code**

K12.3

**ICD-10 code description**

Oral mucositis (ulcerative)

## Primary outcomes

### 1

**Description**

The level of pain and disability

**Timepoint**

At the beginning of the study (before the start of the intervention) and 7, 14, 21, and 28 days after the start

**Method of measurement**

WHO index

**2**

**Description**
Size of lesion
**Timepoint**
At the beginning of the study (before the start of the intervention) and 7, 14, 21, and 28 days after the start
**Method of measurement**
NCI Score

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: In interventional group, photodynamic therapy will be started from emerging the first manifestation of mucositis induced by chemotherapy, once a week for 4 weeks. Indocyanine green will be used for photodynamic therapy and low level laser(LLL) will be applied for activation of this vital stain. After dilution of Indocyanine green (0.1 mg/ml), it will be applied to lesions and after ten minutes low level laser with wave length 808 nm and dose of 50 J/cm2 will be radiated on oral lesions of participants.
**Category**
Treatment - Other

**2**

**Description**
Control group: In the control group, after dilution of Indocyanine green(0.1mg/ml), it will be applied to lesions and after ten minutes patients will receive sham laser.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Namazee hospital
**Full name of responsible person**
Fatemeh Lavaee
**Street address**
Namazee Sq, Zand St, Namazi hospital
**City**
Shiraz
**Province**
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**Postal code**
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**2**

**Recruitment center**
**Name of recruitment center**
Amir oncology hospital
**Full name of responsible person**
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**Street address**
Station 11, Fahang shahr
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7187915998
**Phone**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Fars Province Governor Office
**Full name of responsible person**
Mohammad Hadi Imanieh
**Street address**
Imam Hossein Sq.
**City**
Shiraz
**Province**
Fars
**Postal code**
7134858888
**Phone**
+98 71 3233 8025
**Email**
Info@farsp.ir
**Grant name**
**Grant code / Reference number**
15398-216959
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Fars Province Governor Office
**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**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Shiraz University of Medical Sciences

**Full name of responsible person**
Fatemeh Lavaee

**Position**
Associate Professor of Oral and Maxillofacial Medicine Department

**Latest degree**
Specialist

**Other areas of specialty/work**
Dentistry

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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**