Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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

lavaeef@sums.ac.ir

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
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Fars
Postal code
71936-13311
Phone
+98 71 3647 4332
Email
nemazee_inf@sums.ac.ir

2

Recruitment center
Name of recruitment center
Amir oncology hospital
Full name of responsible person
Fatemeh Lavaee
Street address
Station 11, Fahang shahr
City
Shiraz
Province
Fars
Postal code
7187915998
Phone
+98 71 3632 3532
Email
amirhp@sums.ac.ir

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

Street address
Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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