

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation the Efficacy of Photobiomodulation Therapy with 660 nm Diode Laser on Treatment of Radiotherapy- Induced Oral Mucositis in Head and Neck Cancer Patients: A Randomized Clinical Trial

Protocol summary

Study aim

Determination of the Efficacy of Photobiomodulation Therapy with 660 nm Diode Laser on Treatment of Chemo radiotherapy- Induced Oral Mucositis in Head and Neck Cancer Pat

Design

Phase 3 double-blinded control trial on 30 patients, Randomisation was computerized with concealed randomization sequence carried out at an excel software

Settings and conduct

This study will be conducted on patients with oral mucositis induced by radiotherapy to the head and neck region in Shohadaye Tajrish Hospital, by randomization process, patients were divided into treatment (photobiomodulation therapy) and control (sham photobiomodulation therapy. patients and outcome assessors were blinded to the treatment

Participants/Inclusion and exclusion criteria

Inclusion: Patients with Karnofsky Performance Status equal to or more than 60% Life expectancy equal to or more than 3 months presence of Oral mucositis with at least grade 1 Exclusion: previous radiotherapy to the head and neck Systemic disease

Intervention groups

Patients with oral mucositis receiving photobiomodulation therapy with 660 nm diode laser

Main outcome variables

Grade of oral mucositis (WHO scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230923059490N1**

Registration date: **2023-10-01, 1402/07/09**

Registration timing: **prospective**

Last update: **2023-10-01, 1402/07/09**

Update count: **0**

Registration date

2023-10-01, 1402/07/09

Registrant information

Name

Neda Hakimiha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 396 4604

Email address

ned.hakimiha@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Efficacy of Photobiomodulation Therapy with 660 nm Diode Laser on Treatment of Radiotherapy- Induced Oral Mucositis in Head and Neck Cancer Patients: A Randomized Clinical Trial

Public title

Evaluation of the effects of photobiomodulation therapy on oral ulcers induced by radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with equal or more than 60% Karnofsky Performance Status Life expectancy equal or more than 3 months Clinical confirmation of oral mucositis with minimum grade 1

Exclusion criteria:

Previous history of radiotherapy to head and neck region
Other systemic diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

We will generate random numbers using the Random Number Generation command in Excel. If these generated numbers are even, the patient is assigned to the intervention group, and if it is odd, the patient is assigned to the control group. Each of the groups to which 15 patients are completed, the generated numbers corresponding to that group are removed from the random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Patients: For all patients in both intervention and control groups photobiomodulation therapy with a diode laser will be done, but in the control group laser will be in off mode, and patients can't recognize the on or off status of the laser device due to wearing laser safety goggles. 2. Outcome assessor: the outcome assessor will be blind to the type of treatment that patients have received

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of laser application in medical sciences research center, shahid beheshti

Street address

Shohadaye tajrish hospital, Tajrish square.

City

Tehran

Province

Tehran

Postal code

1989934370

Approval date

2023-08-09, 1402/05/18

Ethics committee reference number

IR.SBMU.LASER.REC.1402.016

Health conditions studied

1

Description of health condition studied

Oral mucositis induced by radiotherapy to head and neck

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description

Oral mucositis grade measured by WHO scale

Timepoint

Before intervention, during treatment session , 4 weeks after intervention

Method of measurement

WHO (World Health Organization) grading Scale for oral mucositis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with oral mucositis receiving photobiomodulation therapy with low level 660 nm diode laser

Category

Treatment - Devices

2

Description

Control group: Patients with oral mucositis receiving sham photobiomodulation therapy (laser in off mode)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Neda Hakimiha

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Shohadaye Tajrish Hospital, Tajrish square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Neda Hakimiha

Street address

Shohadaye tajrish hospotal, Tajrish square, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Neda Hakimiha

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data related to the main outcome

When the data will become available and for how long

Starting 6 months post-publication

To whom data/document is available

Medical doctors/ dentists

Under which criteria data/document could be used

The decision will be taken after evaluation of the request

From where data/document is obtainable

E-mail to the corresponding author

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

up to one month after receiving the request via e-mail, the answer will be sent.

Comments