Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 912 396 4604

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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 compleieted, 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 reseaerch center, shahid behe
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 mucositits 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 receving 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
Street address
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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
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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
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Ph.D.
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Dentistry
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Person responsible for updating data

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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