Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Diode low-level laser therapy on treatment of mucositis induced by chemoradiotherapy in H&N cancer patients referring to Guilan(Rasht) dental college:A single- blind randomized clinical trial

Protocol summary

Study aim

Assessing he effectiveness of Diode low-level laser therapy on treatment of mucositis induced by chemoradiotherapy in H&N cancer patients

Design

Randomized single blinded clinical trial having control group,with parallel groups Sample size:36 patients

Settings and conduct

Laser in areas affected by mucositis with a wavelength of 810 nm and time of 30 seconds per 1 cm2.Laser treatment begins on the day of diagnosis of mucositis and lasts for up to three consecutive days (a total of 4 days).Patients in the control group kept the mouthwash of Diphenhydramine + Almgs (50-50% in combination) at 15 ml every 6 hours for 30 seconds in the mouth and discharged. The investigator make the desired treatment, and the second person will be aware of the changes in both The team. A written agreement form for patients is completed. Place of conducting trial is in surgery department of dental school

Participants/Inclusion and exclusion criteria

Inclusion criteria: head and neck cancer, receive chemotherapy regimen, oral mucositis stage3,4 .Exclusion criteria: Patients with open mouth limitation (less than 1cm2), relapse during treatment, taking any medication for the prevention and treatment of mucositis, inability to perform mucositis treatment and lack of oral hygiene observance.

Intervention groups

In the test group, Diode portable low-power In the control group, combinational mouthwash

Main outcome variables

Evaluation of changes in pain and severity of lesion and patient's quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040863N1**
Registration date: **2018-12-03, 1397/09/12**
Registration timing: **retrospective**

Last update: **2018-12-03, 1397/09/12**
Update count: **0**

Registration date

2018-12-03, 1397/09/12

Registrant information

Name

Safa Motevasseli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 0862

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-16, 1397/04/25

Expected recruitment end date

2018-11-04, 1397/08/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of Diode low-level laser therapy on treatment of mucositis induced by chemoradiotherapy in H&N cancer patients referring to Guilan(Rasht) dental college:A single- blind randomized clinical trial

Public title
Effectiveness of Diode low-level laser therapy on treatment of mucositis induced by chemoradiotherapy in H&N cancer patients referring to Guilan(Rasht) dental college:A single- blind randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Head and neck cancer Receiving Chemotherapy and Radiation Therapy Getting oral mucositis stage3,4
Exclusion criteria:
Restricted opening of the mouth (less than 1cm2) that does not allow the use of laser on the tissue. Relapse during treatment Taking any medication to prevent and treat mucositis Failure to perform mucositis treatment process Inability to observe oral hygiene

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **36**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Random numbers table

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only participants are unaware of the allocation of study groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences Research Center
Street address
End of the Lacan Road - 2 Km to Fouman - Facing Caspian Restaurants and Facade - University Complex in Guilan University of Medical Sciences
City
Rasht
Province
Guilan
Postal code
4194173774

Approval date
2018-06-11, 1397/03/21

Ethics committee reference number
IR.GUMS.REC.1397.096

Health conditions studied

1

Description of health condition studied
oral mucositis

ICD-10 code
K12.3

ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
The amount of pain

Timepoint
Laser: From the onset of the lesion / Day 4 ofTreatment / One week after treatment. mouthwash: From the beginning of the lesion for one month.

Method of measurement
Based on the VAS index

2

Description
severity of lesion

Timepoint
Laser: From the onset of the lesion / Day 4 ofTreatment / One week after treatment. mouthwash: weekly From the beginning of the lesion for one month.

Method of measurement
Based on the WHO

3

Description
length of treatment

Timepoint
Sum of Severity of Mucositis Severity of Days from the onset of symptoms of grade 3 and 4

Method of measurement
number of days

4

Description
quality of life
Timepoint
Laser: From the onset of the lesion / Day 4 ofTreatment / One month after treatment. mouthwash:weekly From the beginning of the lesion for one month.
Method of measurement
based on FACT_HN & OMWQ _ HN

Secondary outcomes

empty

Intervention groups

1

Description
Control group: combined mouthwash: kept the mouthwash of Diphenhydramine + Almgs (50-50 in combination) at 15 ml every 6 hours for 30 seconds in the mouth and then spitting
Category
Treatment - Drugs

2

Description
Intervention group: low_level Diode laser:The laser is applied in mucositis areas with a wavelength of 810 nm and a time of 30 seconds per 1 cm2
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Oral and maxiofacial Surgery, Faculty of Dentistry, Gilan
Full name of responsible person
Safa Motevasseli
Street address
End of Lacan Road - 2 Km to Fouman - Facing Caspian Restaurants and Facade - University of Guilan University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
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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
Rasht University of Medical Sciences
Proportion provided by this source
50
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
Rasht University of Medical Sciences
Full name of responsible person
Shadi Barati
Position
Dentistry student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Position
Assistant professor

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Other areas of specialty/work
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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
preserve Secrets of the patients

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

Statistical Analysis Plan
Not applicable

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

Clinical Study Report
Not applicable

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