

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 the 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 + Almg (50-50% in combination) at 15 ml every 6 hours for 30 seconds in the mouth and discharged. The investigator made 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 stage 3,4
.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 Motevasseleli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 0862

Email address

safa.motevaseli@gums.ac.ir

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 of Treatment / 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 of Treatment / 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 of Treatment / 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 + Almg (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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Email

smotevassellee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Safa Motevasseli

Street address

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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

Street address

Ansarieh

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4515755589

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Safa Motevasseli

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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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