

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of low level laser effect in prevention of chemoradiation-induced oral mucositis in patients with oral cavity cancer

Protocol summary

Summary

The aim of this study is to determine the effect of laser therapy employed to prevent oral mucositis resulting from chemoradiation. This study is a random single blind one. The patients with healthy oral mucosa receiving radiotherapy and chemotherapy for their oral cavity and salivary glands with any reason for the first time with the age range of 12-70 will participate in this study. The patients with the history of chemoradiation, pregnancy, diabetes and light sensitivity are excluded from the study. A total of 46 patients will be divided into 2 groups of 23 individuals. The selection procedure will be as follows. The patients referring will be assigned a number drawn from a box where numbers 1 to 50 is already put in it. A number is taken from the box for the first patient and if the number is odd, the patient will be assigned to the experimental group and if the number is even, he/she will be assigned to the control group. The next person with the same age and gender will be assigned to the opposite group. That is, if the first person is a 63 year old female and has the odd number, the second 60 year old female will be sent to the control group. If the next patient does not match the first one, he/she will be randomly assigned according to odd/even number. Both groups of chemoradiation regimen will have cisplatin in a dose of 30 mg/m² every week (intravenous infusion), and 4-5 hours before or after that, radiotherapy with daily administration of 180- 200 cgray, 5 days a week will be carried out. All the patients will rest for 2 days (conventional method). All selected patients will be receiving radiotherapy for their oral cavity and salivary glands. They will receive chemotherapy in combination with radiation at the same day for 5 successive days with wave length of 630 nanometers, power of 30 mw and dose of 5 j/cm². The radiation will target 10 spots about 8mm in diameter in oral cavity. In the laser off group, laser therapy with off device will be followed. The patients in both groups will be examined by the researcher every other day for 30 days, and the required

information will be gathered in data collection forms. At the end of the treatment, the degree of oral mucositis, xerostomia and the patients' satisfaction will be analyzed.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014040817182N1**

Registration date: **2014-05-10, 1393/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-10, 1393/02/20

Registrant information

Name

Firouz Pouralibaba

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-12-29, 1391/10/09

Expected recruitment end date

2013-12-30, 1392/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of low level laser effect in prevention of chemoradiation-induced oral mucositis in patients with oral cavity cancer

Public title

The effect of low power laser as a prophylaxis of oral mucositis in patients with cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The patients receiving radiotherapy for their oral cavity and salivary glands for the first time in the 12-70 age range with the healthy oral mucosa; patients whose karnofsky performance status is equal or more than 60; life expectancy more than six months; white blood cell more than 1500 and platelets more than 100000; having a written consent from the patient after the necessary explanations by researcher. Exclusion criteria: The patients with the history of chemoradiation, pregnancy, diabetes and light sensitivity.

AgeFrom **12 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **46****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In the laser off group, laser therapy with off device will be followed.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

Street address

3th floor, No 2 central building, Tabriz University of Medical Sciences, Golgasht st, Tabriz

City

Tabriz

Postal code

5166614713

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

92224

2**Ethics committee****Name of ethics committee**

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Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

92224

Health conditions studied**1****Description of health condition studied**

Chemoradiation-induced mucositis

ICD-10 code

K13.7

ICD-10 code description

Other and unspecified lesions of oral mucosa

Primary outcomes**1****Description**

Oral mucositis

Timepoint

15 visits every other day for 30 days

Method of measurement

Examination, inquiry, registration according to WHO mucositis Scale

Secondary outcomes**1****Description**

Xerostomia

Timepoint

15 visits every other day for 30 days

Method of measurement

Examination, inquiry, registration according to LENT
soma criteria

2

Description

Quality of life

Timepoint

Before and one month after intervention

Method of measurement

EORCT-C30 questionnaire

Intervention groups

1

Description

Intervention group: The patients will receive laser therapy for 5 successive days with wave length of 630 nanometers, power of 30 mw and dose of 5 j/cm². The radiation will target 10 spots about 8mm in diameter in oral cavity.

Category

Prevention

2

Description

Control group: In the laser off group, laser therapy with off device will be followed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy Ward of Tabriz Imamreza Hospital

Full name of responsible person

Alireza Naseri

Street address

Imamreza Hospital, Golgasht St, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht St, Tabriz, Iran

City

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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

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Laleh Naseri

Position

Post-graduate student, Department of Oral Medicine, Dentistry Faculty, Tabriz University of Medical

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty