Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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 1to 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

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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.
Age
From **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
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Street address
3th floor, No 2 central building, Tabriz University of Medical Sciences, Golgasht st, Tabriz
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Tabriz
Postal code
5166614713
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 Word 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
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Tabriz

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
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Full name of responsible person
Laleh Naseri
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Person responsible for updating data

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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