Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation the effect of photodynamic therapy on pain and size of chemotherapy induced mucositis

Protocol summary

Summary

Thirty patients with bilateral chemotherapy induced oral mucositis older than 6 years old with consent form will enrolled in the study. Lesions in each patient will be accidentally divided to two groups of intervention side and control side. Both sides will be applied by methylen blue. After 10 min for activation of this dye, low level laser (Azor-ZK-OZ number 242 made in Russia) will be used. Photodynamic therapy will be started from emerging the first manifestation of chemotherapy induced mucositis on day 1, 3, 5. Laser irradiation with low level laser with 660 nm wave length, 19.2 J/cm2 dose for 10 min will be performed. Control side will be irradiated by sham laser. The patients will be followed a week after last session of photodynamic therapy (day12) . Patients and the researcher who measures the scores are blind to the each group treatment (double blind).The participants will be randomized accidentally by block randomization. Each patient will be examined by an oral medicine specialist and size and mucositis grade of oral lesion will be evaluated according to WHO and NCI scores every session before starting photodynamic therapy and before follow up session on day 12.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707108585N4**
Registration date: **2017-08-15, 1396/05/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-08-15, 1396/05/24

Registrant information

Name

Fatemeh Lavaee

Name of organization / entity

Shiraz Dental School

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2017-06-21, 1396/03/31

Expected recruitment end date

2017-10-01, 1396/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of photodynamic therapy on pain and size of chemotherapy induced mucositis

Public title

The effect of photodynamic therapy on mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patients with bilateral chemotherapy induced mucositis; patients over 6 years old; sign the consent form Exclusion criteria: Patients with diabetic mellitus; allergic to the Methylen blue stain

Age

From **6 years** old to **139 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Science, Zand street, Shiraz, Fars

City

Shiraz

Postal code

Approval date

2017-06-11, 1396/03/21

Ethics committee reference number

IR.SUMS.REC.1396.61

Health conditions studied

1

Description of health condition studied

chemotherapy induced oral mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

size of lesion

Timepoint

day1,3,5,12

Method of measurement

NCI score

2

Description

pain, disability

Timepoint

day1,3,5,12

Method of measurement

WHO score

3

Description

weight of patient

Timepoint

day1,3,5,12

Method of measurement

balance

Secondary outcomes

empty

Intervention groups

1

Description

Interventional side: In interventional side, photodynamic therapy will be started from emerging the first manifestation of mucositis induced by chemotherapy, every other day for 3 times. Methylen blue (MB) will be used for photodynamic therapy and low level laser(LLL) [Azor-ZK-OZ number 242 made in Russia] will be applied for activation of this vital stain. After dilution of Methylen blue(0.05 mg/ml), it will be applied to lesions and after ten minutes low level laser with wave length 660 nm, power 25mw and dose 19.2 J/cm2 will be radiated on oral lesions of participants for 10 min.

Category

Treatment - Other

2

Description

Control side: In the control side after dilution of methylen blue (0.05 mg/ml), it will be applied to lesions and after ten minutes patients will receive sham laser.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person
Fatemeh Lavaee
Street address
Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran
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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Basir Hashemi
Street address
Shiraz university of Medical Science, Zand street, Shiraz
City
Shiraz
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 of Shiraz 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
Shiraz University of Medical Sciences
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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