Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of low level laser effect in Prevention of chemotherapy-induced mucositis in patients with cancer referred to Emam Ali hospital in year 1389

Protocol summary

Summary

The aim of this study is to evaluate low level laser effect in prevention of chemotherapy induced mucositis. This is a Double Blind Randomized Clinical Trial in which, 60 patients who have over 6 months hope for life and platelet count more than 100000 are randomly assigned into intervention or control group. The patients in the intervention group will receive 30mw laser in 10 points of the mouth before every period of chemotherapy while the control group will receive extinct laser with the same period of time. The patients in both groups will be visited every 2 weeks during laser therapy (6 months) and 2 weeks after the intervention and intensity of oral muscositis by using WHO standard scale from 0-4, Xerostomia by LENT SOMA scale from 1-4, and pain score by VAS from 0-10 will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811033133N1**
Registration date: **2010-11-20, 1389/08/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-11-20, 1389/08/29

Registrant information

Name

Fateme Arbabi Kalati

Name of organization / entity

Dental school of Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 1814

Email address

farbabi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2010-06-01, 1389/03/11

Expected recruitment end date

2011-06-01, 1390/03/11

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 chemotherapy-induced mucositis in patients with cancer referred to Emam Ali hospital in year 1389

Public title

Evaluation of low level laser effect in prevention of oral mucositis in patients with cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with Karnofsky Performance status equal or more than 60, hope for life more than 6 months, absence of previous chemotherapy toxicity, WBC count equal or more than 1500, platelet count equal or more than 100000 /ml, patients who sign informed consent Exclusion criteria: Simultaneous radio therapy with chemotherapy or previous radiotherapy in head and neck, head and neck surgery cause of

malignancy, Denture or something like that, Pregnancy, infection

Age
No age limit

Gender
Both

Phase
N/A

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
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor for Reseach, Zahedan University of Medical Sciences

Street address
Vice-chancellor for Reseach, Zahedan University of Medical Science, Khalije Fars Highway

City
Zahedan

Postal code

Approval date
2010-07-04, 1389/04/13

Ethics committee reference number
89-1149

Health conditions studied

1

Description of health condition studied
Chemotherapy 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
Every 14 days

Method of measurement
WHO standard scale(0-4)

Secondary outcomes

1

Description
Xerostomia

Timepoint
Every 14 days

Method of measurement
LENT SOMA scale (1-4)

2

Description
Pain

Timepoint
Every 14 days

Method of measurement
VAS

Intervention groups

1

Description
In study group 30 mw laser with wave length 630 nm and 5j/cm2 dosage was used in ten points of the mouth.

Category
Prevention

2

Description
In control group sham laser was used in ten points of the mouth.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Ali Hospital

Full name of responsible person

Street address

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.H.Mahmudzade Sagheb

Street address

Zahedan University of Medical Sciences, Khalije Fars Highway

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Vice-chancellor for Reseach

Full name of responsible person

Dr. Abasalt Borji

Position

Vice-chancellor for Reseach

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Fateme Arbabi Kalati, Dr. Farshid Arbabi Kalati

Position

Assistant Professor, Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr.Fateme Arbabi Kalati, Dr. Farshid Arbabi Kalati

Position

Other areas of specialty/work

Street address

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Postal code

Phone

Fax

Email

Web page address

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