

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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 mucositis 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 radiotherapy 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 Research, Zahedan University of Medical Sciences

**Street address**

Vice-chancellor for Research, Zahedan University of Medical Science, Khaliije 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/cm<sup>2</sup> 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, Khaliije 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****Street address**

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+98 54 1341 6706

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farbabi@razi.tums.ac.ir

**Web page address**

### 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****Street address**

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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****City****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*