

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Efficacy of low-level Diode laser therapy (810nm) in controlling the gag reflex in dental radiography

#### Protocol summary

##### Study aim

To reduce Gag reflex during dental procedures

##### Design

Clinical trial with control group (opposite side of the individual) with parallel groups of 26 people. In this study, no randomization is chosen and all individuals with Gag reflex are being involved in the study. Each person receives a low-level laser at right side of the body and on the left side, colored laser light as a placebo is given to the participants

##### Settings and conduct

This clinical trial study was performed on 26 dentist patients aged 20 to 40 years who were referred to the dental radiology center using XCP

##### Participants/Inclusion and exclusion criteria

Patients between the age of 20 and 40 who are referred for intraoral radiographs experience nausea / health / consent to participate in the study

##### Intervention groups

In this study, 26 people who need to have a dental radiography and feel gag reflex will be involved. After obtaining written and informed consent, each person will be compared with himself, so that this study is based on 26 people who have a gag reflex and have referred to the radiography department of the dental school. Initially, the GAG reflex is measured before the intervention. Low level diode laser (Elexxion) with continuous wavelength of 810 nm and 400  $\mu$ m fiber is being utilized on the right side of the body (with a diameter of 1.1 cm) with a power of 300 mW for 60 seconds. It will be used at the PC6 point and then dental radiography will be taken, the severity of nausea (CGP) and the Gag reflex are measured. In the next step, on the left side of the body, only the colored laser light is used as a placebo and a dental radiography is taken and the Gag reflex is determined again.

##### Main outcome variables

Gag reflex

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191008045033N1**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **retrospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

##### Registration date

2021-01-30, 1399/11/11

##### Registrant information

##### Name

mahya farsadeghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3345 0571

##### Email address

mahyafarsadeghi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-28, 1398/06/06

##### Expected recruitment end date

2019-09-28, 1398/07/06

##### Actual recruitment start date

2019-09-01, 1398/06/10

##### Actual recruitment end date

2019-10-05, 1398/07/13

##### Trial completion date

2019-10-12, 1398/07/20

##### Scientific title

Efficacy of low-level Diode laser therapy (810nm) in controlling the gag reflex in dental radiography

#### Public title

Efficacy of low-level Diode laser therapy (810nm) in controlling the gag reflex in dental radiography

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All patients who require dental radiography

##### Exclusion criteria:

All patients who had normal Gag reflex

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 26

Actual sample size reached: 26

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Zanjan University of Medical Sciences

##### Street address

Azadi Ave., Jomhoriye Eslami Blvd., Zanjan town

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4515613191

#### Approval date

2018-08-28, 1397/06/06

#### Ethics committee reference number

IR.ZUMS.REC.1897.78

## Health conditions studied

### 1

#### Description of health condition studied

Gag reflex

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Gag reflex

#### Timepoint

Before & after laser therapy

#### Method of measurement

Presence or severity of gag reflex

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: In this study, 26 people who need to take a dental radiography and feel gag reflex will be involved. After obtaining informed consent each person will be compared to himself. Continuous wavelength of 810 nm diode laser with 400- $\mu$ m fiber is placed on the target site (with a diameter of 1.1 cm) and with a power of 300 mW will be projected on the PC6 point for 60 seconds.

#### Category

Treatment - Devices

### 2

#### Description

Control group: In this study, the opposite side of the individuals is control group. After low level laser radiation and receiving dental radiography, the opposite side of the same person receives only red colored laser light (placebo effect) and then dental radiography is taken and the gag reflex intensity will be measured.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Zanjan University of Medical Sciences

##### Full name of responsible person

Mohsen Alavi

##### Street address

Haj Ahmad Mahdavi Ave., Shahrak Karmandan.,

Zanjan  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515613191  
**Phone**  
+98 24 3314 8100  
**Email**  
dentist@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Dr. Mina Mohebbian  
**Street address**  
Shahrak Karmandan  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515613191  
**Phone**  
+98 24 3314 8100  
**Email**  
dentist@zums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Zanjan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mahya Farsadeghi  
**Position**  
Dentist  
**Latest degree**

Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shahrak Karmandan  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515613191  
**Phone**  
00 98 24 3348100  
**Email**  
mahyafarsadeghi@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Robab Noormohammadi  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shahrak karmandan  
**City**  
Zanjan  
**Province**  
Zanjan  
**Postal code**  
4515613191  
**Phone**  
+98 24 3314 8100  
**Email**  
robab.noormohammadi@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Mahya Farsadeghi  
**Position**  
dentist  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Shahrak Karmandan  
**City**  
Zanjan  
**Province**  
Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3314 8100

**Email**

mahyafarsadeghi@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

after intervention reports

**When the data will become available and for how long**

1400

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

email

**From where data/document is obtainable**

Co responding author

**What processes are involved for a request to access data/document**

There is no more detail

**Comments**