

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 μ 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)

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+98 24 3345 0571

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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- μ 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

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Haj Ahmad Mahdavi Ave., Shahrak Karmandan.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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Latest degree

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Person responsible for updating data

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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