

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The Effect of Low Level Diode Laser (810nm) Therapy on CV-24 Acupuncture Point in Controlling Gag Reflex of Patients during Intraoral Radiographs

Protocol summary

Study aim

1-Determining the effectiveness of low diode laser in inhibiting nausea reaction in patients between 18 and 50 years old with mild, moderate and severe gag reflex requiring periapical (PA) intraoral radiographs

Design

Cross-sectional clinical trial in a single blind with a sample size of 35 people

Settings and conduct

The present study will be performed at Zanjan Dental School on 35 patients between 18 and 50 years old who have referred for periapical radiography of maxillary posterior teeth. In this study, after obtaining informed consent to participate in the study from clients, in order to eliminate the effect of anxiety as a disturbing factor, patients' level of anxiety is first determined by the Corah Dental Anxiety Scale and only people with the same level of anxiety should be included in the study. Two radiographs will be taken from each person. The first graphic will be done by placing the laser probe on the CV-24 acupuncture point (without laser radiation) and the second graphic after the low-power laser irradiation will be done on the CV-acupuncture point. 24 will be prepared

Participants/Inclusion and exclusion criteria

Sample inclusion criteria: being 18 to 50 years old / need to prepare intraoral radiographs for diagnosis and dental treatment / nausea during radiography / not pregnant / not breastfeeding

Intervention groups

Two radiographs will be taken from each person. The first graphic will be taken by placing the laser device probe on the CV-24 acupuncture point (without laser radiation) and the second graphic will be prepared after the low-power laser irradiation on the CV-24 acupuncture point

Main outcome variables

Anxiety and fear caused by dental procedures; Inhibition

of gag reflex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211217053437N1**

Registration date: **2021-12-23, 1400/10/02**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

Robab Noormohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3336 9810

Email address

dr.noormohammadi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-27, 1400/10/06

Expected recruitment end date

2022-01-26, 1400/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Low Level Diode Laser (810nm) Therapy on CV-24 Acupuncture Point in Controlling Gag Reflex of Patients during Intraoral Radiographs

Public title

The Effect of Low Level Diode Laser (810nm) Therapy on CV-24 Acupuncture Point in Controlling Gag Reflex

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Need to prepare intraoral radiographs for diagnosis and dental treatment Suffering from gag reflex while taking radiographs Having satisfaction

Exclusion criteria:

being during breastfeeding Being pregnant

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The present study will be performed as a one-way blind clinical trial (participants only). Two radiographs will be taken from each person. The first graphic will be taken by placing the laser device probe on the CV-24 acupuncture point (without laser radiation) and the second graphic will be prepared after the low-power laser irradiation on the CV-24 acupuncture point. will be

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences , Azadi Square, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4514685748

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.ZUMS.REC.1400.383

Health conditions studied**1****Description of health condition studied**

Gag reflex

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Gag reflex rate based on Classification of Gagging Problem index

Timepoint

Before the intervention, after the placebo intervention, after the actual intervention

Method of measurement

Classification of Gagging Problem

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Selected specimens require periapical radiographs of the maxillary posterior teeth on both sides for dental diagnosis and treatment, and also have mild, moderate, or severe nausea reflexes based on the GFP classification index. After obtaining informed consent to participate in the study from the clients, two radiographs will be taken from each person. The first radiograph by placing the laser probe on the CV-24 acupuncture point (without laser radiation) and the second radiograph after laser irradiation CV-24 will be prepared at the acupuncture point. The laser used is a diode laser (Ellexion) with a continuous wavelength of 810nm. The tip of the probe rests on the skin at point CV-24 and is projected at 300 mW for 60 seconds. CV-24 is the point on the face in the center of the mentolabial groove, between the lower lip and chin.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Dentistry School

Full name of responsible person

Robab Noormohammadi

Street address

School of Dentistry, Central Campus of Zanjan
University of Medical Sciences, Above Ayatollah
Mousavi Hospital, Dr. Sabouti Blvd., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4514484475

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

Alireza Shoghly

Street address

School of Dentistry, Central Campus of Zanjan
University of Medical Sciences, Above Ayatollah
Mousavi Hospital, Dr. Sabouti Blvd., Zanjan

City

Zanjan

Province

Zanjan

Postal code

4514484475

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

Robab Noormohammadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 7, Nasim Building, Deljoyi Ave., East Zeynabiye
Blvd., Middle Saedi Town

City

Zanjan

Province

Zanjan

Postal code

4514667092

Phone

+98 24 3336 9810

Email

dr.noormohammadi@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Robab Noormohammadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 7, Nasim Building, Deljoyi Ave., East Zeynabiye
Blvd., Middle Saedi Town

City

Zanjan

Province

Zanjan

Postal code

4514667092

Phone

+98 24 3336 9810

Fax

Email

Dr.noormohammadi@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Robab Noormohammadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 7, Nasim Building, Deljoyi Ave., East Zeynabiye Blvd., Middle Saedi Town

City

Zanjan

Province

Zanjan

Postal code

4514667092

Phone

+98 24 3336 9810

Fax**Email**

Dr.noormohammadi@zums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any kind of statistical analysis is allowed on the delivered data

From where data/document is obtainable

Dr.Robab Noormohammadi

dr.noormohammadi@zums.ac.ir

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

The applicant can submit his / her request via the said email. The requested files will be sent to him as soon as possible.

Comments