

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of low-level laser therapy on controlling gag reflex while taking periapical radiographs

Protocol summary

Study aim

Evaluation of low-level laser therapy on controlling gag reflex while taking periapical radiographs

Design

In this study, for phase 2 of the clinical trial, 26 patients referred to the School of Dentistry of the Islamic Azad University of Isfahan were selected based on the inclusion criteria. For randomization, 13 patients referred on the even day were in the intervention group and 13 patients referred on the odd day were placed in the control group. The study was performed as a single-blind study and patients did not know whether the laser was turned on or off.

Settings and conduct

Prior to low-power laser treatment, the pressure from intraoral imaging was restored by imaging film in the posterior region of the mouth. Patients then marked the amount of nausea felt on the prepared vas line After 1 minute and drinking half a glass of water, the first group of patients underwent low power laser irradiation at pc-6 The second group of patients were treated with a silent laser and the laser radiation was simulated

Participants/Inclusion and exclusion criteria

Existence of severe gag reflex while taking periapical radiographs based on the report of the radiology department of the dental school Patients with facial malignancy, a history of seizures, or a thyroid tumor or pregnancy are not included in the study.

Intervention groups

The intervention group was treated with low power laser In the control group, all conditions for laser treatment were simulated, but laser irradiation was not performed In both groups, VAS was measured 3 times before and after irradiation and 2 months later

Main outcome variables

The amount of gag reflex felt that was marked on the VAS line

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049262N1**

Registration date: **2020-12-14, 1399/09/24**

Registration timing: **retrospective**

Last update: **2020-12-14, 1399/09/24**

Update count: **0**

Registration date

2020-12-14, 1399/09/24

Registrant information

Name

amin jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3621 5001

Email address

drjafariamin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-06, 1398/09/15

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2020-05-02, 1399/02/13

Trial completion date

2020-07-03, 1399/04/13

Scientific title

Effect of low-level laser therapy on controlling gag reflex while taking periapical radiographs

Public title

Effect of low-level laser therapy on controlling gag reflex while taking periapical radiographs

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of severe gag reflex while taking periapical radiographs based on the report of the radiology department of the dental school

Exclusion criteria:

Pregnancy Malignancy in the facial area History of seizures Thyroid tumor

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 26

Actual sample size reached: 26

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, 13 patients referred on the even day were in the intervention group and 13 patients referred on the odd day were placed in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient does not know if the laser is on or off

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan Azad University

Street address

University Blvd, Arqavanieh, Jey Street

City

Isfahan

Province

Isfahan

Postal code

81551-39998

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.IAU.KHUISF.REC1398.204

Health conditions studied

1

Description of health condition studied

Gag reflex

ICD-10 code

R11.0

ICD-10 code description

Nausea

Primary outcomes

1

Description

Grade of Gag reflex

Timepoint

At the beginning of the visit-After treatment-2 month later

Method of measurement

VAS line

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of Behsaz gostar low level laser with 660 nm wave length and power of 3 j on pc6 point

Category

Treatment - Other

2

Description

Control group: Placebo , Off laser

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Azad University Dental Clinic

Full name of responsible person

Amin Jafari

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University Blvd, Arqavanieh, Jey Street

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81551-39998
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The Islamic Azad University of Isfahan
Full name of responsible person
Majid Toghiani
Street address
University Blvd, Arqavanieh, Jey Street
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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

The Islamic Azad University of Isfahan

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
The Islamic Azad University of Isfahan
Full name of responsible person
Amin Jafari
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work

Dentistry
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Person responsible for updating data

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

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Marked VAS of the patient

When the data will become available and for how long

Start of the access from year2020

To whom data/document is available

All researchers from universities

Under which criteria data/document could be used

All analyses are allowed

From where data/document is obtainable

Amin Jafari mail :drjafariamin@gmail.com

00989133066331

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

Written request by email Review the application within a week Share information by email

Comments