

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

Protocol summary

Study aim

effect of low level laser acustimulation on gag reflex

Design

this parallel group single blind phase 2-3 randomised trial was performed on 30 - allocated by site to case and control groups - .

Settings and conduct

30 patients were enrolled from Mashhad Dental School . before impression gag reflex severity was measured by GPI (GAG PREVENTION INDEX) including : 1- tolerance of alginate tray until complete setting 2- tolerance of alginate tray just in initial placement 3- tolerance of empty tray 4- intolerance of tray in oral cavity to assess subjective gag reflex severity VAS(Visual Analog Scale) was used . in a ruler numbering 0 to 10 . zero representing no gag reflex and 10 representing the worst gag reflex even experienced. number of vomiting cycles also was registered . in intervention group low level laser (Ga-Al-As) 810nm was irradiated for 1 minute to cv 24 and P6 acupuncture points . after irradiation impression was achieved in 3 mins and severity of gag reflex was registered .in control group all steps were similar except that laser was switched off.this was performed to assess placebo effect.

Participants/Inclusion and exclusion criteria

patients admitted to Mashhad Dental school needing alginate impression for prosthodontic or orthodontic treatment ,20 to 60 years old suffering from severe gag reflex

Intervention groups

in intervention group GaAlAs 810 nm,200mw low level laser was applied on P6,Cv24 acupuncture points for 1 minute. the skin was disinfected by alcohol and the laser probe was applied on 1 cm distance from skin . in control group all situation was similar except that laser was switched off.

Main outcome variables

gag reflex severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080906001216N4**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **retrospective**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

Pegah Mosannen Mozaffari

Name of organization / entity

research center of Mashhad dental faculty, Mashhad University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

2018-06-22, 1397/04/01

Scientific title

comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

Public title

effect of low level laser acustimulation on gag reflex management

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

patient admitted to Mashhad Dental School suffering severe Gag reflex need Alginate impression for denture fabrication or orthodontic treatment

Exclusion criteria:

disagreement to participate in trial

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

allocation to two groups by <http://www.randomizer.org> (two groups A and B)

Blinding (investigator's opinion)

Single blinded

Blinding description

patient was blind about sham laser

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Mashhad University of Medical Sciences-Research
Ethics Committee

Street address

Vakil Abad BLV

City

Mashhad

Province

Razavi Khorasan

Postal code

911735984

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.047

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

gag reflex

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes**1****Description**

gag reflex management

Timepoint

just after intervention

Method of measurement

GPI = gag prevention index

Secondary outcomes

empty

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

Intervention group: in this group low level laser acustimulation on accumuncture points for controlling gag reflex (cv24 ,pc6) was performed before obtaining maxillary impression

Category

Prevention

2**Description**

Control group: in this group sham laser (placebo) was placed on accumuncture points for controlling gag reflex (cv24 ,pc6) before obtaining maxillary impression.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Dental School

Full name of responsible person

Pegah Mosannen Mozafari

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Pegah Mosannen Mozafari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

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

data including demographic data signs and symptoms
and intervention results will be released

When the data will become available and for how long

2 months after article publication

To whom data/document is available

academic staff

Under which criteria data/document could be used

the data can be used in further studies with citation to
main article

From where data/document is obtainable

pegah mosannen mozafari

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

email communication , the data will be sent in 4 weeks

Comments