

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the effect of low-level laser therapy on pain control caused by Elastomeric Separators in Orthodontic patients

Protocol summary

Study aim

Determine the effect of low power laser on pain control caused by elastomeric separators in orthodontic patients

Design

A clinical trial with a control group with parallel, two-blind, randomized groups

Settings and conduct

Place of study: The office of Dr. Seyed Amir Hossein Mirhashemi and The Dr. Seyed Reza Rasouli. Method of study: In this double blind study, the patient and the observer are not informed on which study groups they are in. The data analyser is not involved in the laser procedure. The samples are randomly allocated to the study groups by means of block random method (blocks of size 4) using the Excel software. The last two samples are assigned to the study groups by means of simple randomization method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 25 volunteer patients who are candidate for orthodontic treatment, both male and female, age between 18 and 30 years old. Non-inclusion criteria: Having specific systemic disease, having specific mental problem, having specific dental or periodontal problem, using specific medication

Intervention groups

Intervention group : laser radiation in one quadrant of mouth, 810 nm diode laser will be radiated in 3 dose in three different times on patients. The patient's pain will be measured using the VAS method based on self-perception at different times and recorded the data and the amount of pain between the two groups are compared. Control group : non-radiation laser in opposite side of the same jaw in the same person The control group receives an inactive radiation as placebo. The method of measuring pain and radiation times is as same as intervention group.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190610043853N1**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **retrospective**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

Registration date

2020-01-14, 1398/10/24

Registrant information

Name

Seyed Amirhossein Mirhashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7793 4596

Email address

mirhashemi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of low-level laser therapy on pain control caused by Elastomeric Separators in Orthodontic patients

Public title

Evaluation Of the effect of Low-level laser therapy on pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Twenty-five volunteer patients who are eligible for orthodontic treatment Both male and female Age between 18 and 30 years old

Exclusion criteria:

Having specific Systemic disease Having specific Mental problem Having specific Dental or Periodontal problem Using specific Medication

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were randomly allocated to the study groups by using block random method (blocks of size 4) using in Excel software. The last two samples were assigned to the study groups by simple randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and the observer (data collector) are not informed about which study groups they are placed in. In regards to blinding, the patient in the non-radiation group receives a placebo light, which is not a laser type and can be a light cure device. The person who does data analysis is not involved in the intervention procedure.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Faculty of Dentistry, Not reaching the Hakim highway, above the Atomic Energy Organization, End of the North Amirabad St, Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1397.167

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

pain

Timepoint

0hours, 2 hours, 6hours, 24hours, 72hours and 5 days after laser

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: laser radiation in one quadrant of mouth The study is Split-mouth design so the intervention group and the control group are both in the same person. One side of patient (one half jaw) is as the intervention group and the other half as the control group which receiving placebo radiation. 24 hours before placing separators on the upper first molar, the first dose of low power 810 nm diode laser with a power of 0.3 W

and energy of 3.75 J / cm² and spot area = 0.8 cm² and a continuous 10 seconds will be radiated on the location of radiation. The second radiation will be done at the time of placement and the third dose in 24 hours after the separators are placed. The patient's pain will be measured using the VAS method based on self-perception at 0, 2, 6, 24, 72 hours and 5 days after placement of separators, and recorded the data and the amount of pain between the two groups are compared.

Category

Prevention

2

Description

Control group: non-radiation laser in opposite side of the same jaw in the same person. The control group receives an inactive radiation as placebo at times like the intervention group. The method of measuring pain is as same as intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Seyed Amirhossein Mirhashemi Office

Full name of responsible person

Seyed AmirHossein Mirhashemi

Street address

Unit 23, Second floor, No. 107, Between Shirazi and Sheikh Bahai, Mulla Sadra St.

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2

Recruitment center

Name of recruitment center

Dr. Seyed Reza Rasouli

Full name of responsible person

Seyed Reza Rasouli

Street address

Unit 6- Second floor- No. 104- nwxt to the Ghobadian St.- Jordan St.

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Phone

+98 21 8878 6343

Email

shiva_shahii@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahrayian

Street address

Tehran University of Medical Sciences, Faculty of Dentistry, before the Hakim highway, after the Atomic Energy Organization, at the end of the North Amirabad street, Kargar street.

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Phone

+98 21 8801 5950

Email

mirhashemi@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Amirhossein Mirhashemi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Tehran University of Medical Sciences, Faculty of Dentistry, Not reaching the Hakim highway, above the Atomic Energy Organization, End of the North Amirabad St, Kargar Ave.

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Amirhossein Mirhashemi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Position

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Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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 received after the receipt of the article resulting from the study can be shared

When the data will become available and for how long

Access 4 months after the publication of the paper resulting from the research

To whom data/document is available

Researchers working in academic and academic institutions

Under which criteria data/document could be used

All analyzes that do not need to identify samples and re-access them to data can be done

From where data/document is obtainable

Refer to the author of the article

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

Perform correspondence with the submitter and send the information file

Comments