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 palcebo 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.

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8821 1640

Email

shiva_shahii@yahoo.com

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.

City

Tehran

Province

Tehran

Postal code

1439955991

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.

City

Tehran

Province

Tehran

Postal code

1439955991

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.

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5950

Email
mirhashemi@tums.ac.ir

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
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.

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5950

Email
mirhashemi@tums.ac.ir

Person responsible for updating data

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.

City
Tehran

Province
Tehran

Postal code
1439955991

Phone
+98 21 8801 5950

Email
mirhashemi@tums.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 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