Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of 980 nm diode laser irradiation on pro-inflammatory cytokines and mini-screw stability

Protocol summary

Study aim

this study aimed to determine the effect of 980 nm diode laser irradiation on mini-screw stability and the concentration of IL-1B and TGF-B1 in PMCF at four time points following mini-screw placement.

Design

This study had a split-mouth design in order to decrease the confounding factors. LLLT was performed by the second examiner in a double-blind fashion such that the patient and the first examiner were blinded to the group allocation of each quadrant and the selected quadrant for laser therapy. Selection of the maxillary quadrant for laser therapy was done randomly by the second examiner. Laser was also used for the control quadrant with the same timing but in off mode. The primary stability of mini-screws was measured using Periotest M . PMCF samples were collected to measure the concentration of IL-1B and TGF-B1.

Settings and conduct

the research will done in orthodontic department of the Faculty of dentistry of Shahid Sadoughi University of Medical Sciences

Participants/Inclusion and exclusion criteria

- Patients requiring extraction of maxillary first premolars and anterior retraction.

Intervention groups

Laser was irradiated for 30 s to the occlusal and 30 s to the gingival part of the mini-screw during four cycles in the laser group. Selection of the maxillary quadrant for laser therapy was done randomly by the second examiner (laser group). Laser was also used for the control quadrant with the same timing but in off mode. By doing so, the patients were blinded to the group allocation of quadrants. Laser was irradiated at four time points of T0 (at the time of placement of mini-screw), T1 (at 1 week), T2 (at 1 month) and T3 (at 3 months).

Main outcome variables

The primary stability of mini-screws will measure with Periotest M . Inflammation around the mini-screws will evaluate by measuring the concentration of IL-1β and TGF-β1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191008045028N1**
Registration date: **2019-12-11, 1398/09/20**
Registration timing: **retrospective**

Last update: **2019-12-11, 1398/09/20**
Update count: **0**

Registration date

2019-12-11, 1398/09/20

Registrant information

Name

Somaye Kordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3621 2222

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s.kordi3314@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-06-11, 1398/03/21

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-06-20, 1398/03/30

Trial completion date
2019-10-15, 1398/07/23

Scientific title
Effect of 980 nm diode laser irradiation on pro-inflammatory cytokines and mini-screw stability

Public title
Effect of diode laser irradiation on pro-inflammatory cytokines and mini-screw stability

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with bimaxillary dentoalveolar protrusion or class II division I malocclusion requiring extraction of maxillary first premolars and anterior retraction. Good oral hygiene Signing the informed consent forms by the patients or their parents

Exclusion criteria:
systemic disease history of extraction of other permanent teeth taking medications affecting the level of pro-inflammatory cytokines such as non-steroidal anti-inflammatory drugs and corticosteroids during the study period or in the past one month prior to the onset of treatment periodontal disease or radiographic evidence of bone loss pregnancy during the orthodontic treatment

Age
From **15 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **12**
Actual sample size reached: **11**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done.the side of laser irradiation and the control side is determined by the coin toss of each patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
Banding and bonding of teeth perform by the first examiner for all patients. Low level laser perform by the second examiner in a double-blind fashion such that the patient and the first examiner blind to the group allocation of each quadrant and the selected quadrant for laser therapy.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shahid sadoughi University of Medical Sciences

Street address
Faculty of Dentistry, Dahaye Fajr BLV, Imam Ave, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
89195/165

Approval date
2018-05-30, 1397/03/09

Ethics committee reference number
IR.SSU.REC.1397.031

Health conditions studied

1

Description of health condition studied
patients with class II division I malocclusion or bimaxillary protrusion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary stability of mini-screws

Timepoint
at four time points: T0 (1 h after mini-screw placement), T1 (1 week later), T2 (at 1 month) and T3 (at 3 months).PTV was measured at the above mentioned four time points and one hour after laser irradiation

Method of measurement
The primary stability of mini-screws was measured by Periotest M and reported as Periotest value (PTV). At each time point, samples were collected from the PMCF to assess the concentration of IL-1B and TGF-B1

2

Description
Inflammation around the mini-screws

Timepoint
at four time points: T0 (1 h after mini-screw placement), T1 (1 week later), T2 (at 1 month) and T3 (at 3 months).The samples were collected at the aforementioned four time points and one hour after laser

irradiation and prior to the measurement of PTV

Method of measurement

PMCF samples were collected using high-purity filter papers used as paper strips to measure the concentration of IL-1β and TGF-β1.A cotton roll was used for isolation of the area and the mini-screw site was dried with air spray for 15 seconds. The paper strip was inserted into the gingival sulcus around the mini-screw and remained there for 60 s. If the Periostrip was contaminated with blood or saliva, sampling was repeated. Immediately after PMCF collection, the paper strips were transferred into sterile 1.5 mL microtubes containing 250 µL of phosphate buffered saline. Parafilm (Bemis; Neenah, Wisconsin, USA) was used to seal the tubes. The vials were stored at -20°C until collection of all samples and onset of experiment. The PMCF samples were used to measure the concentration of IL-1β using a kit designed for this purpose (Diaclone SAS, Besancon, France) and TGF-β1 using the respective kit (IBL International GMBH, Germany) by enzyme-linked immunosorbent assay according to the manufacturers' instructions.

Secondary outcomes

1

Description

At each time point, samples were collected from the PMCF to assess the concentration of IL-1B and TGF-B1

Timepoint

at four time points: T0 (1 h after mini-screw placement), T1 (1 week later), T2 (at 1 month) and T3 (at 3 months)

Method of measurement

The PMCF samples were used to measure the concentration of IL-1B using a kit designed for this purpose (Diaclone SAS, Besancon, France) and TGF-B1 using the respective kit (IBL International GMBH, Germany) by enzyme-linked immunosorbent assay according to the manufacturers' instructions

Intervention groups

1

Description

Intervention group:Mini-screws were placed between the roots of maxillary second premolar and first molar. Diode laser was irradiated with 980 nm wavelength and 100 mW output power in continuous-wave mode for 30 seconds to the occlusal and 30 seconds to the gingival part of the mini-screw at four time points: T0 (1 h after mini-screw placement), T1 (1 week later), T2 (at 1 month) and T3 (at 3 months) in one quadrant of the maxilla (laser group).

Category

Treatment - Devices

2

Description

Control group: Simultaneously the other quadrant of the maxilla underwent pseudo-application of laser .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontics Department of School of Dentistry, Yazd Shahid Sadoughi University of Medical Sciences.

Full name of responsible person

Soghra Yassaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Masoud Mirzaei

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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

Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Somaye Kordi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Department of Orthodontic, Faculty of Dentistry, Dahaye Fajr BLV, Imam Ave, Yazd, Iran

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
Medical doctor

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

Title and more details about the data/document
Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To promote motivation and science

From where data/document is obtainable

s.kordi3314@yahoo.com somaye kordi

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

Email the responsible author

Comments