

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of low level laser and local anesthetic gel on patient pain and discomfort during orthodontic mini screws insertion compared with local anesthesia: a clinical trial

Protocol summary

Study aim

determining the patient's pain immediately after placing the mini-screw on the infiltrating injection site
determining the patient's pain immediately after placement of mini-screw in low power laser group and local anesthesia gel according to VAS criteria Compare the patient's pain and discomfort on both sides

Design

a split-mouth clinical trial without control group involving 25 patients

Settings and conduct

private clinic

Participants/Inclusion and exclusion criteria

patients over 18 years old undergoing fixed orthodontic treatment patients candidate for receiving mini-screw during treatment

Intervention groups

The present study is split-mouth and the mini-screws are placed on one side using infiltrated anesthesia and on the opposite side a combination of local anesthesia gel and low power laser will be used.

Main outcome variables

Low power laser and local anesthetic gel have a better effect on controlling pain and discomfort than infiltration injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200616047801N1**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Hamid Jahedsaravani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3310 3076

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low level laser and local anesthetic gel on patient pain and discomfort during orthodontic mini screws insertion compared with local anesthesia: a clinical trial

Public title

Effect of low level laser and local anesthetic gel on patient pain and discomfort during orthodontic mini screws insertion compared with local anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age undergoing fixed orthodontic treatment patients candidate for receiving a mini-screw during treatment

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

This is a split-mouth study in which local anesthesia is used on one side and anesthesia gel and low power laser on the other side.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

khazar Blvd, Tooba dental clinic

City

Sari

Province

Mazandaran

Postal code

4816895475

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IR.MAZUMS.REC.1399.427

Health conditions studied

1

Description of health condition studied

Evaluation of the patient's pain and discomfort during orthodontic mini-screw placement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain and discomfort control due to the use of local anesthesia gel and laser compared to local anesthesia without injection

Timepoint

At the beginning of the study and 12, 24 hours after inserting the mini-screw

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of local anesthetic infiltration on one side which is a candidate for receiving a mini-screw

Category

Treatment - Drugs

2

Description

Intervention group: The use of local anesthesia gel and low power laser on the other side which is a candidate for a mini-screw

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic, Shahriar 3 building

Full name of responsible person

Dr farhad sobuti

Street address

shahriar3 building- Farhang Ave

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Province

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Postal code

4818611894

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Farhad_sobouti@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hamid Jahed

Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

Specialist

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Person responsible for updating data

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Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Postal code

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Phone

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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