

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

###### Phone

+98 11 3310 3076

###### Email address

hamid.jahed.63@gmail.com

##### 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

**City**

Sari

**Province**

Mazandaran

**Postal code**

4818611894

**Phone**

+98 11 3332 1253

**Email**

Farhad\_sobouti@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr farhad sobouti

**Street address**

Tooba dental clinic, Khazar Blvd

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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

#### Contact

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Dr Farhad Sobouti

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

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**Position**

Dental student

**Latest degree**

Medical doctor

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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