

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Evaluation of the effect of mini-screw-facilitated micro-osteoperforation on the rate of orthodontic tooth movement

#### Protocol summary

##### Study aim

The objective of this clinical trial study is to evaluate the ability of mini-screw as a micro-perforation device to accelerate canine retraction in orthodontic patients. Additionally, we will investigate the pain and discomfort of the patient during the study.

##### Design

The study is double blind randomized clinical trial with split mouth design.

##### Settings and conduct

Both maxillary canines will be retracted, and movement will be measured every 28 days in three intervals. Pain and discomfort will be monitored with a visual analogue scale.

##### Participants/Inclusion and exclusion criteria

Class II division 1 or Class I bimaxillary dentoalveolar protrusion Mild or no crowding No previous orthodontic treatment No history of systemic disease Good oral hygiene No radiographic evidence of bone loss No history of periodontal therapy and active periodontal disease Probing depth less than 4 mm across the entire dentition No gingivitis or active carious lesion Gingival index and plaque index value less than 1 No smoking

##### Intervention groups

Ten patients with Class II Division 1 or Class I bimaxillary protrusion malocclusion will be selected. Four month after first premolar extraction, just before canine retraction micro-osteoperforation will be created in experimental side of each patient. The control side will not receive micro-osteoperforations.

##### Main outcome variables

rate of canine movement pain and discomfort after micro-osteoperforation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181121041713N1**

Registration date: **2018-11-30, 1397/09/09**

Registration timing: **prospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **0**

##### Registration date

2018-11-30, 1397/09/09

##### Registrant information

###### Name

neda babanouri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3628 0801

###### Email address

babanouri@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-06, 1397/09/15

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of mini-screw-facilitated micro-osteoperforation on the rate of orthodontic tooth movement

##### Public title

effect of micro-osteoperforation on the rate of tooth movement

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

orthodontic patients with Class II division 1 or Class I bimaxillary dentoalveolar protrusion malocclusion mild or no crowding no previous orthodontic treatment no history of systemic disease good oral hygiene no radiographic evidence of bone loss or no history of periodontal therapy and active periodontal disease probing depth less than 4 mm across the entire dentition no gingivitis or active carious lesion gingival index and plaque index value less than 1 no smoking.

#### **Exclusion criteria:**

### **Age**

From **15 years** old to **45 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

### **Sample size**

Target sample size: **10**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

The experimental side will be randomly selected by means of coin tosses to prevent selection bias

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

Three insertions will be created on buccal and palatal area in the control side only in gingival tissue by principle investigator, so both patients and orthodontist administering the treatment will be blind of allocation side

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Science

### **Street address**

central building of Shiraz University of Medical Science, Zand st.

### **City**

Shiraz

### **Province**

Fars

### **Postal code**

7134814336

### **Approval date**

2018-06-24, 1397/04/03

### **Ethics committee reference number**

1396-01-37-15681

## **Health conditions studied**

### 1

#### **Description of health condition studied**

rate of orthodontic tooth movement

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

rate of canine retraction

#### **Timepoint**

28 days- 56 days- 84 days

#### **Method of measurement**

electric digital caliper- Visual Analogue Scale

## **Secondary outcomes**

### 1

#### **Description**

Pain after micro-osteoperforation

#### **Timepoint**

on the day of canine retraction - subsequently at 24 hours

#### **Method of measurement**

Visual Analogue Scale (VAS).

## **Intervention groups**

### 1

#### **Description**

Intervention group: 1 mm micro-osteoperforation on the buccal and palatal bone

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: perforation only on the gingiva

#### **Category**

Treatment - Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shiraz dental school

**Full name of responsible person**

Mahtab Memarpour

**Street address**

Dental School, Ghomabad Ave., Ghasraldasht St.

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**Email**

dental@sums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

**Street address**

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

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vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

1396-01-37-15681

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Neda Babanouri

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Neda Babanouri

**Position**

Assistant professor

**Latest degree**

Specialist

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

بیمارگیری قبل از 11 دیماه کامل خواهد شد

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available