

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Sep 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

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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-osteo perforation 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

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Dental School, Ghomabad Ave., Ghasraldasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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

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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

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Person responsible for updating data

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Phone

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