Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 71 3628 0801

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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-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
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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
Dentistry

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Person responsible for updating data

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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