Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Combination of Micro-osteoperforation and a Vibration Device on Orthodontic Tooth Movement : A Prospective Randomized Clinical trial

Protocol summary

Study aim
Determining the effect of the combination of micro-osteoperforation and a vibration device on the rate of orthodontic tooth movement.

Design
Controlled clinical trial with parallel group, single-blinded, randomized, on 20 patients. The "Balanced Block Randomization" method is used for randomization.

Settings and conduct
Three months after extraction of the first maxillary premolars, canine retraction begins in both groups in the Orthodontic Department, School of Dentistry, Tehran University of Medical Sciences. Micro-osteoperforations are performed on the buccal and palatal surfaces, right and left sides of the maxilla, just before the canine retraction. Patients in the intervention group use a vibration device from the initial stage of retraction, 5 minutes a day. Alginate impressions are taken at the beginning of the study, immediately before retraction, and 28 days after the onset of canine retraction.The amount of orthodontic movement of canine teeth is measured on patients' dental casts using a digital caliper. Blinding of the patients and clinical researcher is not possible; but blinding of the persons responsible for data collection and outcome evaluation is possible.

Participants/Inclusion and exclusion criteria
Inclusion criteria : age range (18 to 45 years) , maxillary canine teeth fully erupted, need to extract both first maxillary premolars, existence of 3 mm space after initial alignment, good oral hygiene. Exclusion criteria : systemic diseases affecting bone metabolism, take any medication, periodontal disease, smoking, pregnancy.

Intervention groups
Intervention group: receives micro-osteoperforations on both sides (right and left) of the maxilla along with using a C-shaped vibration device. Control group: receives micro-osteoperforations on both sides of the maxilla without using a vibration device.

Main outcome variables
Rate of orthodontic tooth movement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190108042293N1**
Registration date: **2021-07-31, 1400/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-31, 1400/05/09**
Update count: **0**

Registration date
2021-07-31, 1400/05/09

Registrant information

Name
Sarvin Sarmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-31, 1400/05/09

Expected recruitment end date
2021-08-31, 1400/06/09

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Combination of Micro-osteoperforation and a Vibration Device on Orthodontic Tooth Movement : A Prospective Randomized Clinical trial

Public title
The Effect of Combination of Micro-osteoperforation and a Vibration Device on Orthodontic Tooth Movement
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range : 18 to 45 years Maxillary canine teeth fully erupted Need to extract both first maxillary premolars Existence of 3 mm space after initial alignment Good oral hygiene
Exclusion criteria:
Systemic diseases affecting bone metabolism Take any medication Periodontal disease Smoking Pregnancy
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the "Balanced Block Randomization" method will be used. In this method, 4 blocks (envelopes) of equal size are prepared. In each block, sheets are randomly assigned to the control group (B) and/or the intervention group (A) using the RAND option of Excel software. The randomization process will be performed by the Methodology and Research Consultant of the study and the clinical researcher will not be aware of the type of intervention until the study begins (allocation concealment). The person performing the randomization process, places the letters A as the intervention group and the letters B as the control group on sheets inside the sealed envelopes. These envelopes will be numbered from 1 to 4 . At the beginning of the study and the arrival of patients (participants), envelope 1 to envelope 4 will be used, respectively, and when working on the patient, the envelope will be opened and the type of intervention will be determined.
Randomization unit: Individual Randomization tool: Excel software
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients (participants) blinding is not possible because one of the study interventions is vibration that is perceived by the patients. Blinding the clinical researcher is also not possible. Because the responsible persons for data collection and outcome evaluation are different from the practitioner (clinical researcher) and while collecting data and evaluating the outcome, they do not know which control and / or intervention group the patient belongs to, blinding of the persons responsible for data collection and outcome evaluation is possible.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
North Karegar St , Tehran , Iran
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۹۵۵۹۹۱
Approval date
2019-12-18, 1398/09/27
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1398.163

Health conditions studied

1

Description of health condition studied
Orthodontic Treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Rate of orthodontic tooth movement
Timepoint
At the beginning of the study, immediately before canine retraction, and 28 days after the onset of canine retraction
Method of measurement

Digital caliper with an accuracy of 0.01 millimeter and dental casts

Secondary outcomes

1

Description
The level of pain caused by micro-osteoperforation
Timepoint
The day of appliance placement , the day of canine retraction, and subsequently at 24 hours, 7 days, and 28 days after canine retraction
Method of measurement
Numerical rating scale

2

Description
The level of patient's drooling caused by micro-osteoperforation and the use of a vibration device
Timepoint
The day of appliance placement , the day of canine retraction, and subsequently at 24 hours, 7 days, and 28 days after canine retraction
Method of measurement
Numerical rating scale

Intervention groups

1

Description
The intervention group: receives micro-osteoperforations on both sides (right and left) of the maxilla along with using a C-shaped vibration device (Vpro5, Propel Orthodontics).
Category
Treatment - Devices

2

Description
The control group: receives micro-osteoperforations on both sides (right and left) of the maxilla without using a vibration device.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Sciences, School of Dentistry, Department of Orthodontics
Full name of responsible person
Sarvin Sarmadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Dental Research Institute of Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Sarvin Sarmadi

Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthodontist
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Individual unidentifiable data of the participants including age, sex, type of malocclusion and data obtained from the study such as the effect of intervention on the rate of orthodontic tooth movement.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Faculty members of the universities of medical sciences
Under which criteria data/document could be used
Using data for systematic review
From where data/document is obtainable
Applicants can refer to the corresponding author " Dr. Sarvin Sarmadi" to get the study data. Postal address: Department of Orthodontics, School of Dentistry, Tehran University of Medical Sciences, North Karegar St., Tehran, Iran. Postal code: 1439955991 Email : sarmadis@sina.tums.ac.ir Phone : 0098 21 88015801
What processes are involved for a request to access data/document
After receiving the request of an applicant and consulting the first and the corresponding authors of the article, the documents will be delivered to the applicant within 1 working month.
Comments