

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

Country

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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

AgeFrom **18 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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

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Tehran

Province

Tehran

Postal code

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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

Dental Research Institute of Tehran University of Medical Sciences

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

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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