

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Combination of Micro-osteoperforation and a Vibration Device on Inflammatory Factors IL-1 β , RANKL, CCL2, and TNF- α in Orthodontic Tooth Movement: A Prospective Randomized Clinical trial

Protocol summary

Study aim

The Effect of Combination of Micro-osteoperforation and a Vibration Device on Inflammatory Factors IL-1 β , RANKL, CCL2, and TNF- α in Orthodontic Tooth Movement

Design

Controlled clinical trial with parallel group, single-blind, randomized, on 20 patients. Excel software rand function was used for randomization

Settings and conduct

Three months after the first premolars are extracted, canine retraction begins in both groups. MOPs are performed in the buccal and palatal region distal to the canine teeth just before canine retraction. Patients in the experimental group also use a vibrating device from the initial stage of retraction, 5 minutes a day. GCF is collected before orthodontic treatment, immediately before canine retraction, 24 hours later, 7 days later, and 28 days later. Immediately the paper strips are transferred to plastic vials containing Tris Buffer solution. Vials containing samples are sent to the immunology laboratory to measure inflammatory factors .

Participants/Inclusion and exclusion criteria

Age range (18 to 45 years); canine fully erupted; Need to extract both first maxillary premolars; Existence of 3 mm space after initial alignment; Good oral hygiene

Intervention groups

The experimental group receives MOPs on both sides of the maxilla using a C-shaped vibrating device. The control group receives MOPs on both sides (right and left) of the maxilla without the use of a vibrating device.

Main outcome variables

impact on the treatment duration ; Impact on complications due to prolonged orthodontic treatment time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200928048869N1**

Registration date: **2020-11-05, 1399/08/15**

Registration timing: **prospective**

Last update: **2020-11-05, 1399/08/15**

Update count: **0**

Registration date

2020-11-05, 1399/08/15

Registrant information

Name

Hanane Ghadirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4279 4500

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-04-21, 1400/02/01

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 Inflammatory Factors IL-1 β , RANKL, CCL2, and TNF- α in Orthodontic Tooth Movement: A Prospective Randomized Clinical trial

Public title

The Effect of Combination of Micro-osteoperforation and a Vibration Device on Inflammatory Factors

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18-45 erupted canines need for extraction first maxillary premolars at least 3 mm space after initial alignment good oral hygiene

Exclusion criteria:

systematic disease which have effect on bone metabolism taking 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

Randomization method: Balanced Block Randomization (In this method, blocks are formed based on the considered variables and within each block, half of the intervention people and half are considered as controls).
Randomization unit: individual
Randomization tool: Microsoft Excel

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer is blind and does not know which group the results belong to

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

Dentistry faculty of Tehran university of medical science, North Karegar, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1439900991

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1399.058

Health conditions studied

1

Description of health condition studied

orthodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Increased expression of inflammatory factors(IL-1 β , RANKL, CCL2 and TNF- α) following the use of vibration in orthodontic patients who received MOP.

Timepoint

immediately before canine retraction, 24 hours later, 7 days later, and 28 days later

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group receives MOPs on both sides (right and left) of the maxilla using a C-shaped vibrating device (Vpro5, Propel Orthodontics).

Category

Other

2

Description

Control group: Receives MOPs on both sides (right and left) of the maxilla without the use of a vibration device.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty of Tehran university of medical science, Orthodontics department

Full name of responsible person

Hanane Ghadirian

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Orthodontics department, Dentistry faculty of Tehran university of medical science, North Karegar, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Institute of Tehran University of Medical Science

Full name of responsible person

Mohamadsadegh Ahmadakhoundi

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Dental Research Institute, School of Dentistry, Ghods St, Enqelab St

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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 Science

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

Hanane Ghadirian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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 data of participants including age, sex, type of malocclusion and data obtained from the study such as the effect of intervention on inflammatory factors.

When the data will become available and for how long

6 months after publication of article

To whom data/document is available

scientific members of university of medical science

Under which criteria data/document could be used

data extraction for systematic review

From where data/document is obtainable

Applicants can get help from the corresponding author (Dr. Hananeh Ghadirian). Postal address: Department of Orthodontics, School of Dentistry, Tehran University of Medical Sciences, North Karegar Postal code: 1439955991 Email address: Dr.h.ghadirian@gmail.com

What processes are involved for a request to access data/document

After receiving of the request and consultation with first and corresponding author, we will inform the researcher within a month.

Comments