

The interrelationships between changes in the metabolic state and homeostasis of the bone and injection of a new substance during orthodontic tooth movement

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Registration date 07/05/2024	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/05/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tooth anchorage control is one of the main factors determining the success of orthodontic treatment. The challenge is to design a system that maximizes desirable tooth movements and also minimizes anchorage loss, especially in adult patients demanding a more convenient treatment with orthodontic appliances to control unfavourable tooth movement. Bisphosphonate drugs may reduce orthodontic tooth movement due to their effects on bone turnover. Therefore, the aim of this study is to assess the use of the bisphosphonate drug zoledronic acid to prevent anchorage loss in orthodontic treatment.

Who can participate?

Patients aged 18-25 years old with skeletal class II malocclusion (overbite)

What does the study involve?

Patients will be randomly allocated into two groups to be treated with either zoledronic acid or placebo injection only once before starting the mass retraction, and are followed up until the retraction period ends (6-8 months).

What are the possible benefits and risks of participating?

Bisphosphonates can strengthen tooth anchorage during orthodontic treatment. Bisphosphonates may have side effects at high concentrations, which are not used in this study.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?

April 2022 to June 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)

Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

4244

Study information

Scientific Title

Evaluation of the efficacy of locally injected zoledronic acid in increasing the anchorage during en-masse retraction of the maxillary anterior teeth: a randomized controlled clinical trial

Study objectives

There are a significant differences between the experimental group and the control group in increasing the anchorage during mass retraction of the upper anterior teeth.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 29/08/2022, Scientific research and postgraduate studies council of Damascus (Damascus, Damascus, 0004, Syria; +963 (0)993303359; ap.srd@damascusuniversity.edu.sy), ref: 4244

Study design

Interventional single-center single-blinded randomized parallel-group controlled trial

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Skeletal class II and moderate maxillary protrusion

Interventions

Patients will be randomly allocated into two groups using Microsoft® Excel electronic randomization:

Group 1: Experimental group: the dental arch will first be aligned with wires 0.12, 0.14, 0.16, 16.22, 17.25, 19.25 NITI. Then the upper first premolars will be extracted and then will be applied the zoledronic acid to the patient through local injection mesial to the upper first molar on both the right and left sides and on the vestibular and palatal sides and then mass retraction of the upper anterior teeth will be started.

Group 2: The treatment protocol used in this group is the same as described in the experimental group, but placebo will be applied to the patient instead of zoledronic acid.

The medicinal substance is applied only once during the treatment before starting the mass retraction, and participants are followed up until the retraction period ends (6-8 months).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Zoledronic acid

Primary outcome(s)

1. The amount of slippage of the upper first molars mesially during retraction
2. The inclination of the axes of the upper first molars
3. Rotation of maxillary first molars
4. The height of the alveolar bone in the injection area
5. The thickness of the alveolar bone in the injection area
6. Root resorption of maxillary first molars

Measured using cone beam computed tomography (CBCT) before the start of orthodontic treatment and after the end of the mass retraction

Key secondary outcome(s)

Pain and discomfort following injection measured using the visual analogue score (VAS) at baseline, 1, 3, and 7 days

Completion date

20/06/2024

Eligibility**Key inclusion criteria**

1. Patient who has a second class II as light to medium with $4 < ANB < 8$
2. In the vertical plane, a natural or slight vertical growth pattern
3. Moderate anchorage, where the molar and canine relationships are cusp to cusp
4. The mandibular dental arch is well aligned or slightly crowded and does not require extraction treatment
5. A patient with good oral health and healthy periodontal tissue
6. A patient who does not take any medications
7. A patient who has not undergone previous orthodontic treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

25 years

Sex

All

Key exclusion criteria

1. Patients who have a severe structural defect in the sagittal plane
2. Patients who have a severe horizontal or vertical growth pattern
3. The patient who has moderate to severe crowding in the lower dental arch requires extraction to treat it
4. Patients with general diseases or craniofacial syndromes
5. Pregnant or breastfeeding

Date of first enrolment

01/04/2023

Date of final enrolment

01/12/2023

Locations**Countries of recruitment**

Syria

Study participating centre**Damascus University**

Department of Orthodontics

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Sponsor information**Organisation**

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)**Funder type**

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication