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

Submission date
28/04/2024

Recruitment status
No longer recruiting

Registration date
07/05/2024

Overall study status
Completed

Last Edited
07/05/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 significiant 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

Secondary study design
Randomised parallel trial

Study setting(s)
Medical and other records, University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zoledronic acid

Primary outcome measure
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

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

Overall study start date
01/04/2022

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 crowed 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

Age group
Adult

Lower age limit
18 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
40

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
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Sponsor type
Research council

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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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/01/2025

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