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A new study to minimise the side effects of rapid maxillary expansion

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/07/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/07/2023	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rapid Maxillary Expansion (RME) is a common orthodontic treatment to widen the upper jaw, creating more space for crowded teeth and improving breathing. However, RME may lead to unwanted side effects, including dental and buccal alveolar bone changes, which can weaken tooth anchorage and hinder treatment outcomes. To address this issue, researchers are investigating the potential of Zoledronic Acid (ZA) injection as a preventive measure.

Zoledronic Acid (ZA) is a drug used to treat bone diseases like osteoporosis and to prevent bone loss in certain conditions. It works by slowing down bone breakdown, which could be useful in counteracting the bone changes that occur during RME. By introducing ZA during the RME procedure, orthodontists aim to minimize the negative impact on dental and buccal alveolar bone, thus enhancing the stability of anchored teeth.

The study will use Cone-Beam Computed Tomography (CBCT) as the imaging technique to assess the effectiveness of ZA in preventing bone changes. CBCT is a non-invasive imaging technology that produces detailed 3D images of the oral structures, allowing precise measurements of bone density and tooth movements.

The main objectives of the study are to determine whether ZA injection effectively reduces dental and buccal alveolar bone changes associated with RME and to evaluate its impact on tooth anchorage stability. The findings of this research could contribute to enhancing RME treatment outcomes by minimizing side effects and optimizing the overall orthodontic experience for patients. If successful, ZA injection may become a valuable addition to RME procedures, helping orthodontists achieve better and more predictable results while ensuring long-term dental health.

Who can participate?
Patients requiring RME treatment.

What does the study involve?
Pareints will be randomly divided into two groups. The experimental group will receive ZA injections alongside RME, while the control group will undergo RME without ZA. The CBCT scans will be taken before the procedure and at 3 months after treatment.

What are the possible benefits and risks of participating?
Benefits: Participants may experience improved orthodontic outcomes with minimized side effects, leading to enhanced dental health and aesthetics. Additionally, they contribute to scientific progress by exploring the potential benefits of Zoledronic Acid in orthodontic treatments, possibly benefiting future patients.
Risks: Participants may encounter mild side effects from Zoledronic Acid, such as flu-like symptoms, but serious adverse reactions are rare. Additionally, there might be discomfort or inconvenience related to CBCT scans.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
December 2020 to May 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
765

Study information

Scientific Title
Evaluations of the effect of Zoledronic acid injection on dental and buccal alveolar bone changes following
rapid maxillary expansion by using Cone Beam Computed Tomography (CBCT)

Study objectives
The purpose of this study was to evaluate the effectiveness of Zoledronic acid (ZA)injection in minimizing the side effects of rapid maxillary expansion (RME) on dental and buccal alveolar bone changes anchoring teeth using cone-beam computed tomography (CBCT)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/12/2020, institutional board and ethical review committee of Damascus University (Meza Highway, Damascus, -, Syria; +963 11 212 1635; dean.dent@damascusuniversity.edu.sy), ref: 765

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Side effects of rapid maxillary expansion (RME) on dental and buccal alveolar bone changes

Interventions
The patients were distributed into two groups according to the manual random distribution method, whereby each patient who agreed to participate in the research was asked to withdraw a dark sealed envelope, the number of which reached (32) envelopes, each containing a white sheet bearing the group number (16 sheets for each group), so that the patient was included The group whose number was chosen at random.
Thus, the sample was divided into two main groups: the group of zoledronic acid injections and the group of saline injections before
expansion.
- The first group underwent a subperiosteal injection of zoledronic acid 10 days before expansion
- The second group underwent a subperiosteal injection of saline 10 days before expansion

Where the patient was anesthetized supraperiosteal injection (topical 20% benzocaine gel) followed by local anesthesia (mepivacaine 3%) at the first premolar and upper first molar on the right and left sides, zoledronic acid was injected using an insulin syringe for one time only under the periosteum of the buccal alveolar plate in the middle of the gingival height attached above the root of the tooth to be injected, and a CBCT image was requested (T0).
10 days after the injection, the expander was placed, and expansion began one day after the

placement of the expander.
Expansion was done twice a day (0.4 mm) in the morning and evening until we got an overcorrection of (2-3 mm) and it lasted 7–14 days depending on the degree of deficiency and the severity of resistance to expansion.
After the completion of the rapid maxillary expansion, the skeletal expander was fixed using a tie wire (0.018) and kept inside the mouth and used for retention for 3 months. A CBCT image of the upper jaw was requested after the fixation (T1) was completed. The expander was removed.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
All measurements were carried out in a dark room then recorded and compared between baseline (T0) and 3 months (T1):
1. For the first molar on either side: The long axis (Y) in the sagittal plane was made parallel to the long axis of the mesiobuccal root. The X-axis was made tangent to the trifurcation. This process was also performed for the first molar on the other side. In the axial plane; the X-axis was positioned according to the buccolingual axis of the oval section of the mesiobuccal root and applied. Finally, in the coronal plane; the buccal surface of the root was made parallel to the tomographic vertical plane. The cementoenamel junction (CEJ) and the buccal alveolar crest were identified. Finally, readjustments were made if any change occurred.
2. The loss in buccal bone crest level (BBCL) was measured vertically from the CEJ to the alveolar crest. The buccal bone plate thickness (BBPT) was measured in two axial planes: the furcation plane and 3 mm above that plane, between buccal surfaces of the root and alveolar bone.
3. The same technique was followed to orient CBCT sections for the first premolar with its buccal root. The CEJ was set as a reference to identify two axial planes above it (3 mm and 6 mm) for BBPT because it was difficult to identify the furcation region of the first premolar.
4. The incidence of buccal dehiscence and fenestrations of the anchor teeth was reported. Dehiscence was defined as an increase in the distance between the CEJ and alveolar crest of more than 2 mm based on the normal value of alveolar height. Fenestrations were considered as alveolar bone discontinuation, which exposed a small region of the root and the defect didn't involve the alveolar crest. If the image showed no cortical bone around the root in at least three sequential views, the defect was recorded as a dehiscence or a fenestration.

Key secondary outcome(s)
1. Questionnaires related to pain and discomfort were administered to patients in both groups at the same time of appliance installation. The questions were answered using a visual analog scale (VAS). The VAS consisted of a standard 10-mm metric ruler, where 0 corresponded to minor and 10 to greater levels of pain or discomfort. Patients were asked about the level of pain and discomfort immediately after zoledronic acid injection, 1 day after injection, 7 days after injection and 15 days after injection.
2. Patients were also questioned on the level of adaptation for speech, chewing and swallowing. The guardians' perception of pain and discomfort caused by the therapy was also assessed. The same questionnaire was administered to the patients' guardian 1 month after appliance placement in a separate environment. Parents/guardians were blinded to their child's answers.

Completion date
01/05/2023

Eligibility

Key inclusion criteria
1. Clinical maxillary transverse deficiency
2. Complete emergence of first molars and first premolars
3. Good oral hygiene

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Patients with medical situations or drug therapy that affected orthodontic treatment and periodontal health
2. Poor oral hygiene
3. Previous orthodontic treatment
4. Patient who didn’t correctly follow the protocol of activation or didn’t return for appointments

Date of first enrolment
01/01/2021

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty Of Dentistry
Meza Highway
Damascus
Syria
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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 during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes