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Accelerating orthodontic tooth movement

Submission date
22/05/2022

Recruitment status
No longer recruiting

Registration date
31/05/2022

Overall study status
Completed

Last Edited
08/04/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Static magnetic fields have an effect on the cells in the periodontal (gum) tissues by increasing the absorption and placement of bone and increasing the rate of tooth movement. They could be used to speed up the movement of teeth during orthodontic treatment and relieve pain and discomfort because the duration of orthodontic treatment is one of the factors that patients take into consideration when making a treatment decision. The aims of this study are to evaluate the use of static magnetic fields in accelerating orthodontic tooth movement and to study the levels of acceptance and discomfort of patients.

Who can participate?
Patients with bimaxillary protrusion (protruding upper and lower teeth) and requiring extraction of the first upper and lower premolars

What does the study involve?
Before applying the trans-palatal arch (an orthodontic appliance), the upper first premolars will be extracted. Rectangular stainless steel arch wires will be inserted, then after 1 month, the canine retraction will be started. A low-intensity static magnetic field will be applied to one of the two sides of the upper arch through a wire carrying magnets. The upper canine retraction will be done using springs. The force level will be controlled every 2 weeks. Retraction will be stopped when the canines on both sides are correctly positioned. Dental casts will be used to measure the movement of the upper canine and the first molars every 30 days.

What are the possible benefits and risks of participating?
The static magnetic field may speed up orthodontic tooth movement with low levels of pain and discomfort.

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

Where is the study starting and how long is it expected to run for?
February 2021 to October 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Nataly Alqaisi
nataly.qaisi@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Nataly Alqaisi

ORCID ID
https://orcid.org/0000-0003-3008-261X

Contact details
Damascus University
Mezzeh Autostrade
Damascus
Syria
80567
+963 (0)947688800
nataly.qaisi@gmail.com

Additional identifiers

Protocol serial number
906

Study information

Scientific Title
Effectiveness of low-intensity static magnetic field in the accelerating of orthodontic tooth movement and levels of acceptance and discomfort: a randomized controlled trial

Study objectives
1. Applying a static magnetic field accelerates orthodontic tooth movement (upper canine)
2. A static magnetic field reduces pain and discomfort

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/11/2021, scientific research and postgraduate studies council of Damascus University (Damascus, Syria 80789; +963 (0)993303359; info@damascusuniversity.edu.sy), ref: 906

Primary study design
Interventional

Study design
Interventional single-center single-blinded randomized split-mouth controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Orthodontic tooth movement

Interventions
The trial will evaluate the effect of a low-intensity static magnetic field in the accelerating of orthodontic tooth movement in retraction of the upper canine. Before applying the trans-palatal arch, the upper first premolars will be extracted. The rectangular stainless steel arch wires (0.019" × 0.025") will be inserted, then after 1 month, the canine retraction will be started. A fixed device containing Nd-Fe-B neodymium-iron-boron magnets is able to retain magnetism permanently. The low-intensity static magnetic field will be applied to one of the two sides of the upper arch through an auxiliary wire carrying magnets, between magnets there is an air gap of 2 mm, where the static magnetic field is, corresponding to the region of the lateral ligament of the canine. The density of the static magnetic field is 414 mt, as the field strength is measured by a millimeter tesla device. The upper canine retraction will be done using NITI springs. The force level will be controlled every 2 weeks. Retraction will be stopped when a class I canine relationship is achieved on both sides. Dental casts will be used for the quantification of the anteroposterior movement of the upper canine and the first molars every 30 days until the class I canine relationship is achieved.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Low-intensity static magnetic field

Primary outcome(s)
1. The effectiveness of the low-intensity static magnetic field in accelerating orthodontic tooth movement in retracting the upper canines compared to traditional methods. Calculation of the lateral movement of the canine (mm/month):
1.1. Duration of upper canine retraction: the months required to complete the retraction procedure will be recorded. Completion of this procedure is expected to occur within 4 months to 6 months. Assessment will be performed by calculating the months required to achieve complete retraction of the upper canine retraction through clinical examination.
1.2. Rate of retraction: the calculation of the rate of retraction will be done once the retraction procedures have finished. Completion of this procedure is expected to occur within 4 months to 6 months. Assessment will be performed on study models. The amount of distance being retracted in millimeters will be divided by the duration of retraction in weeks to give an estimation of the retraction rate. Dental casts will be used for the quantification of the anteroposterior movement of the upper canine every 30 days until the class I canine relationship is achieved.

T0: 1 day before the beginning of canine retraction; T1: after 1 month of retraction; T2: after 2 months of retraction; T3: after 3 months of retraction; T4: after 4 months of retraction; and T5: at the end of retraction (expected to be within 4 months to 6 months)

2. Dentoalveolar changes (loss of anchorage - canine rotation):
2.1. Change in molar positions: T0: 1 day before the beginning of canine retraction; T1: after 1 month of retraction; T2: after 2 months of retraction; T3: after 3 months of retraction; T4: after 4 months of retraction; and T5: at the end of retraction (expected to be within 4 months to 6 months). The amount of distance travelled by the first molars is measured on study models taken at monthly intervals until the end of the retraction phase.
2.2. Change in canine rotation: T0: 1 day before the beginning of canine retraction; T1: after 1 month of retraction; T2: after 2 months of retraction; T3: after 3 months of retraction; T4: after 4 months of retraction; and T5: at the end of retraction (expected to be within 4 months to 6 months). The rotation of the canines is measured on study models taken at monthly intervals until the end of the retraction phase.

Key secondary outcome(s)
1. Acceptance and discomfort measured using the Visual Analogue Scale every 30 days from the 1st day after the activation of canine retraction. Completion of this procedure is expected to occur within 4 months and 6 months.
2. Tooth vitality measured for each canine using ethyl chloride applied by a cotton roll 1 day before the commencement of the retraction phase and at the end of the retraction phase

Completion date
15/10/2022

Eligibility

Key inclusion criteria
1. The patient has a bimaxillary protrusion and needs extraction of the first upper and lower premolars, with the relationship of the canines and molars being first class according to Angle
2. The sagittal skeletal relationship is first or second class
3. Normal or excessive facial height
4. All patients have permanent occlusion
5. Patients have good oral health (plaque index ≤1)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
17

Key exclusion criteria
1. Patients suffering from systemic diseases or syndromes
2. Missing permanent maxillary teeth (except third molars)
3. Patients who have impacted teeth
4. Patients who smoke
5. Patient who had previous orthodontic treatment

Date of first enrolment
05/08/2021

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dentistry
Department of Orthodontics
Mezzeh Autostrade
Damascus
Syria
20872

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/04/2024	08/04/2024	Yes	No