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How orthodontic treatment without tooth removal affects dental alignment and bone structure

Submission date 23/08/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/09/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/09/2024	**Condition category** Oral Health	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to explore the changes in teeth and surrounding bone when using a combination of a special orthodontic device (a modified lip bumper) and traditional braces to correct moderate crowding of the lower teeth. The goal is to see how this combination treatment affects the alignment of the teeth and the bone structure.

Who can participate?
Adults aged 18-27 years who have moderate crowding of the lower teeth are eligible to participate in this study.

What does the study involve?
Participants in the study will receive orthodontic treatment to correct their crowded teeth. They will either be treated with a combination of a modified lip bumper and traditional braces or with braces alone. The study will measure changes in the width of the dental arch and the surrounding bone structure during the treatment.

What are the possible benefits and risks of participating?
The combination treatment may help improve the way teeth move during orthodontic treatment, reducing some of the negative effects that can occur with tooth movement. There are no known risks associated with participating 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?
May 2022 to December 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Dentoalveolar changes resulting from combination of modified lip bumper and fixed appliance - MBT prescription during the treatment of mandibular incisors crowding

Study objectives
Using a combination of fixed appilance and lip bumper will alter the type of orthodontic movement and reduce dentoalveolar side effects

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 15/08/2022, Damascus University (Mazzeh highway, Damascus, -, Syria; +963 (11) 339 23223; ap.srd@damascusuniversity.edu.sy), ref: 4069

Study design
interventional two-arm randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Adult patients with moderate crowding in mandible

Interventions
Participants are assigned into the following two groups using simple randomization:
Study group: fixed appliance _ MBT prescription_ and a modified lip bumper.
Control group: fixed appliance _ MBT prescription_ only
Each group will undergo leveling and alignment with the same archwire sequence
The records (cast models and CBCT images) will be obtained at:
T0: before treatment
T1: after 12 month

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Modified lip bumper

Primary outcome measure
Type of orthodontic movement determined upon cephalometric measurements, alveolar bone boundaries changes and root resorption determined on CBCT, arch dimensions changes detected on dental cast at T0: start of the treatment and T1: after one year

Secondary outcome measures

1. Arch dimensions measured using dental casts at T0, T1
2. Bone height and thickness measured using CBCT images at T0, T1

Overall study start date
31/05/2022

Completion date
15/12/2024

Eligibility

Key inclusion criteria
1. Adults 18 - 27 years
2. Mandibular crowding 4 - 6 mm
3. Normal or short face
4. No previous treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
27 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Long face
2. Bad oral health
3. Drugs affect bone metabolism
4. Non compliant patients

Date of first enrolment
04/09/2022

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Syria

Study participating centre
Orthodontic department, Damascus university
Mazzeh highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
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-
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Sponsor type
University/education

Website
http://www.damascusuniversity.edu.sy

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

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

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be shared within planned publications.

IPD sharing plan summary
Published as a supplement to the results publication