

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

Submission date 23/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/09/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 appliance 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 (Mazzeah 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

Study type(s)

Efficacy

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

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Modified lip bumper

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

27 years

Sex

All

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

Mazzeah 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 will be shared within planned publications.

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes