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Measurement of orthodontic tooth movement with dental magnetic resonance imaging

Submission date
11/04/2024

Recruitment status
No longer recruiting

Registration date
11/04/2024

Overall study status
Completed

Last Edited
16/05/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
The objective of this clinical investigation is to examine different types of gums before starting orthodontic treatment and to analyze how the soft and hard tissues around the lower front teeth change during the process of moving them with braces. We will be using a new technique called dental MRI, which doesn't involve radiation like traditional CBCT imaging, to examine the dimensions of both soft and hard tissues around the lower front teeth..

Who can participate?
Adolescent (aged 12 - 18 years) patients with substantial treatment need and crowding in the mandible.

What does the study involve?
In this study, we will examine different types of gums using both clinical assessments and imaging techniques such as CBCT scans and intraoral scans. Additionally, we will use a new method called dental magnetic resonance imaging (MRI), which can show both soft and hard tissues. We will compare the measurements obtained from CBCT and intraoral scanning with those from dental MRI. We're particularly interested in the thickness of the free gingiva, the gingiva above and below the crest of the bone, and the size of the bone around the lower front teeth. Throughout the treatment process, we will monitor the lower front teeth of the patients for five months using dental MRI.

What are the possible benefits and risks of participating?
Benefits of participation are the combination of radiologically assessed soft tissue dimensions and their monitoring throughout the initial treatment phase, ensuring that patients do not undergo unnecessary surgical procedures such as soft tissue augmentation, while at the same time selecting those who do require such a procedure.
Risks associated with the study interventions include patients experiencing claustrophobia during the MRI scan.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
May 2021 to May 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Linda Schwarz, linda.schwarz@meduniwien.ac.at

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
CPMS1090

Study information

Scientific Title
A novel approach for measurement of orthodontic tooth movement with dental magnetic resonance imaging

Study objectives

There is no statistical significant difference in tissue dimensions in patients before, and after start of orthodontic treatment

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/07/2021, Ethics Committee of the Medical University of Vienna (Borschkegasse 8b, Vienna, 1090, Austria; +43 1 40400 21470; ethik-kom@meduniwien.ac.at), ref: 1654/2021

Study design
Prospective pilot study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Diagnostic, Treatment

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

Health condition(s) or problem(s) studied
Moderate to severe crowding in the mandible

Interventions
2 MRI examinations, one before (T0) and one five months after (T1) start of orthodontic treatment.

Intervention Type
Other

Primary outcome measure
Gingiva and bone thickness around the lower anterior teeth measured using MRI before (T0) and one five months after (T1) start of orthodontic treatment

Secondary outcome measures
Tooth movement measured using MRI before (T0) and one five months after (T1) start of orthodontic treatment

Overall study start date
01/05/2021

Completion date
01/05/2024

Eligibility

Key inclusion criteria
1. Crowding in the mandible of >3mm
2. All permanent teeth in the mandible, no missing teeth in the mandible
3. >12 years of age, orthodontic treatment need (IOTN 4 or 5)

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Claustrophobia
2. Systemic diseases
3. Cranio-facial anomalies
4. Smoking

Date of first enrolment
01/01/2022

Date of final enrolment
15/01/2025

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Sensengasse 2a

Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

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Sponsor type
University/education

Website
https://www.meduniwien.ac.at/web/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
15/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study are not expected to be made avaiable due to the highly sensitive nature of radiologic datasets.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2025	16/05/2025	Yes	No