Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Level of Metalloproteinase Matrix 8 in Gingival Crevicular Fluid of Mandibular anterior teeth with two types of fixed and removable orthodontic retainers

Protocol summary

Study aim

Determination of mean metalloproteinase matrix 8 (in pg) in mandibular anterior teeth in ESSIX and bonded retainers

Design

Clinical trial, two parallel groups, double-blind, randomized to 30 patients, randomization by Random allocation software.

Settings and conduct

The study is performed at Shahid Sadoughi Dental School in Yazd. ESSIX retainer is bandaged for each patient in a session and in the upper jaw, and according to the group in which they are located, in the lower jaw, Retainer wire Hilgers Bond A Braid or ESSIX retainer (by Vacuum thermoforming machine is placed. The gingival fluid of these patients will be sampled on the day of debonding, 30 days later and 90 days later. In this study, the statistical consultant and the head of the laboratory become blind

Participants/Inclusion and exclusion criteria

Inclusion: 1-Patients have been treated with the 022 System and their treatment has been completed with satisfactory correction of malocclusion and appropriate dental alingment.2-The Patient's condition is favorable in terms of general health.3-Absence of Craniofacial Syndromes and Facial Clefts 4-Absence of severe and uncontrolled Caries 5-The Patient should have good oral hygiene and be Periodontally normal. 6-The Patient should have all the anterior Mandibular teeth and the teeth should be of normal shape and size Non inclusion:1-Lack of Patient cooperation to refer 2-Observe poor Periodontal status during the study3-Break and not using the retainer 4-Specific conditions of COVID 19 infection that prevent the Patient from visiting.

Intervention groups

The first intervention group (15 patients) who have ESSIX at the end of treatment and the second intervention group (15 patients) who have a banded retainer at the end of treatment.

Main outcome variables

Metalloproteinase matrix level 8 after orthodontic debonding immediately after debonding, 30 days and 90 days after debonding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210221050435N2**
Registration date: **2021-10-07, 1400/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-07, 1400/07/15**
Update count: **0**

Registration date

2021-10-07, 1400/07/15

Registrant information

Name

Hossein Aghili

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Level of Metalloproteinase Matrix 8 in Gingival Crevicular Fluid of Mandibular anterior teeth with two types of fixed and removable orthodontic retainers

Public title

Level of Metalloproteinase Matrix 8 in Gingival Crevicular Fluid of Mandibular anterior teeth with two types of fixed and removable orthodontic retainers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients have been treated with the 022 System and their treatment has been completed with satisfactory correction of malocclusion and appropriate dental alingment. The Patient's condition is favorable in terms of general health. Absence of Craniofacial Syndromes and Facial Clefts Absence of severe and uncontrolled Caries The Patient should have good oral hygiene and be Periodontally normal. The Patient should have all the anterior Mandibular teeth and the teeth should be of normal shape and size.

Exclusion criteria:

Lack of Patient cooperation to refer Observe poor Periodontal status during the study Break and not using the retainer Specific conditions of COVID 19 infection that prevent the Patient from visiting.

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using Random allocation software version 1.0 under Windows ,we generate a random sequence using a simple random allocation method. In this table, it is specified from 1 to 22 and each number is assigned to an intervention group (A or B). The first eligible patient is assigned number 1, the second patient is assigned number 2 and so on up to 22 patients. In order to blind the random allocation of clients by a third person who is unaware of the interventions, they are placed in intervention groups (A or B) by this table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the Patients and the researcher (who is responsible for sampling of Patients) are aware of the type of retainer in the Mandible. But the person in charge of data collection, the statistician consult who is in charge of data analysis, and the person in charge of the laboratory who will eventually analyze the samples are blinded because the information and samples of patients in all the mentioned steps will be identified only by random numbers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Yazd Shahid sadoughi University of medical science

Street address

Dahe Fajr Boulevard.Imam Reza Street.Shahid Sadoughi University of medical science.Yazd

City

Yazd

Province

Yazd

Postal code

8914881167

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.SSU.REC.1400.013

Health conditions studied

1

Description of health condition studied

Mandibular Retainer at the end of Orthodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of Matrix Metalloproteinase 8 after Orthodontic debonding

Timepoint

Immediately after debonding, 30 days after debonding, 90 days after debonding

Method of measurement
Sampling of the gingival crevice fluid will be done and then the amount of Matrix Metalloproteinase 8 enzyme will be determined with the kit related to the this enzyme .

Secondary outcomes

1

Description
Little irregularity index
Timepoint
Day of debonding, 30 days after debonding, 90 days after debonding
Method of measurement
Evaluation from cast taken from the patient on the days of measurement

2

Description
Overjet
Timepoint
Day of debonding, 30 days after debonding, 90 days after debonding
Method of measurement
Examination in the patient's mouth on the days of measurement

3

Description
Overbite
Timepoint
Day of debonding, 30 days after debonding, 90 days after debonding
Method of measurement
Examination in the patient's mouth on the days of measurement

4

Description
Bleeding after gingival probing
Timepoint
Day of debonding, 30 days after debonding, 90 days after debonding
Method of measurement
Examination in the patient's mouth on the days of measurement

Intervention groups

1

Description
Intervention group: After setting the appointment, for each patient in a session, the ESSIX retainer will be placed in the upper jaw, and according to the group in which they are placed, the banded retainer(Retainer wire Hilgers Bond-A-Braid :Stainless steel, 8-strand, dead soft) will be placed in the lower jaw.At the time of Debonding, the patient is molded and a cast is prepared for him. To make the retainer, after debonding, the patient is molded using alginate.In the retainer bonding session, first the lingual surface of the mandibular incisor teeth is rinsed with water and gently dried with air . Two pieces of dental floss pass through the contact between the lateral and canine on both sides and the retainer is placed in place. Flossing passes over the retainer and the retainer adapts to the lingual surface of the teeth by applying some force.The lingual surface of these teeth is etched with 37% phosphoric acid and rinsed, and then the retainer is bonded to the lingual surface using TRANSBOND composite.The gingival fluid of these patients will be sampled on the day of debonding, 30 days later and 90 days later.
Category
Treatment - Devices

2

Description
Intervention group: After setting the appointment, for each patient in a session, the ESSIX retainer is placed in the upper jaw, and according to the group in which they are placed, the ESSIX retainer is placed in the lower jaw. ESSIX retainer (1 mm thick) by Vacuum ،Thermoforming Machine is also made on the cast prepared by the patient after debanding.The gingival fluid of these patients will be sampled on the day of debonding, 30 days later and 90 days later.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthodontics, School of Dentistry, Shahid Sadoughi University of Medical Sciences, Yaz
Full name of responsible person
Hossein agha Aghili
Street address
The beginning of Deh Fajr Boulevard, Imam Khomeini St
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hosseinaghily@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr.Masoud Mirzaei

Street address
The headquarters of Shahid Sadoughi University of Medical Sciences and Health Services, Bahonar Square, Yazd

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Fax
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Email
dvc.research@ssu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Hossein agha Aghili

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After unidentifying individuals, it is possible to share all values of the metalloproteinase matrix and the irrigularity index and overjet and overbite of patients in both treatment groups.

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Researchers working in academic and scientific institutions and valid scientific research journals

Under which criteria data/document could be used
In order to use the documents of this study for other studies and researches to apply the results

From where data/document is obtainable
Responsible person in this field: Shiva Abdollahi , email address:sh.abdollahi.dds@gmail.com

What processes are involved for a request to access data/document
The applicant can send his request to the above-mentioned email address with his introduction and the reason for the request and receive the information as soon as possible (finally within 7-10 days).

Comments