Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Failure Rates of Orthodontic Brackets Bonded by no-mix and Light Cure Bonding Systems : A Randomized Clinical Trial

Protocol summary

Study aim

Determining the failure rate of bonded brackets with two bonding systems, LightCure and Nomix

Design

A double-blind, randomized clinical trial on 23 patients.

Settings and conduct

This study is a double-blind clinical trial to compare the rate of band failure with two bonding systems Nomix and Light Cure during 12 months in patients referred to a private treatment center. The method of blinding in this study is that except for the therapist and patients, the student participating in the research and the person statistically analyzing the results, will not know the bonding system used in the right and left premolars of the maxillary quadrants. Brackets are bonded with self-cure and light-cure bondings for selected patients as split-mouth in the maxillary premolars. With once a month follow-up, by observing the brackets, the failure rate of the bracket bond will be checked and according to the checklist, the time of the bond failure and the tooth with a bond failure will be recorded by the therapist.

Participants/Inclusion and exclusion criteria

Patients in need of fixed orthodontic treatment with inclusion criteria for no occlusal interference in the posterior region; no caries no presence of congenital anomalies of the facial surface of maxillary premolars. Exclusion criteria: patients with occlusal interference with brackets; the facial surface of maxillary premolars with restoration and fluorosis; caries and the history of bracket bonding

Intervention groups

Fixed orthodontic treatment with split-mouth design by brackets bonded with two groups of light cure and nomix bondings for maxillary premolars for each patient.

Main outcome variables

Bonding system and failure rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052389N2**
Registration date: **2021-10-24, 1400/08/02**
Registration timing: **prospective**

Last update: **2021-10-24, 1400/08/02**
Update count: **0**

Registration date

2021-10-24, 1400/08/02

Registrant information

Name

Maziar Esmailimoghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 3590

Email address

esmailimoghaddam.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-10-12, 1401/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Failure Rates of Orthodontic Brackets Bonded by no-mix and Light Cure Bonding Systems : A Randomized Clinical Trial

Public title

Failure Rates of Orthodontic Brackets Bonded by no-mix and Light Cure Bonding Systems : A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with malocclusion who need fixed orthodontic treatment Patients without age and sex restrictions No occlusal interference in the posterior region No caries and congenital anomalies of the facial surface of maxillary premolars

Exclusion criteria:

Patients with occlusal interactions with brackets Facial surface of maxillary premolars with restoration and fluorosis, caries and previous bracket bond

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **23**

More than 1 sample in each individual

Number of samples in each individual: **2**

Premolars in the maxilla bonded with brackets by different bonding systems

Randomization (investigator's opinion)

Randomized

Randomization description

The bonding material for the upper premolar brackets bond on the left and right is selected randomly, so that in the first patient, for example, the upper left premolar bracket is bonded with a light cure and the upper right premolar is bonded with a self-cure and do this method vice versa in the next patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding in this study is that except for the therapist and patients, the student participating in the research and the person statistically analyzing the results, they wont know the bonding system used in the right and left premolars of the maxillary quadrants

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Resalat Street, above the Modiriat Street next to the emergency, Urmia Medical Sciences Headquarters

City

Orumieh

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-08-25, 1400/06/03

Ethics committee reference number

IR.UMSU.REC.1400.191

Health conditions studied

1

Description of health condition studied

Dental crowding and maxilofacial dentoskeletal abnormalities

ICD-10 code

M26

ICD-10 code description

Dentofacial anomalies [including malocclusion]

Primary outcomes

1

Description

Bracket bond failure

Timepoint

Determining bond failure by observing from the beginning to the end of the study with one-month follow ups

Method of measurement

Number of bonding failure rate of bracket per unit time

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fixed orthodontic treatment with split-mouth design by brackets bonded with two groups

of light cure and Nomix bondings, both with Master-Dent brand, made in the USA on maxillary premolars in each patient, whose teeth are first cleaned with rubber cup and pumice paste and washed and dried with water. After rinsing, the facial surface of the teeth for bracket attachment is etched with 37% phosphoric acid for 20 seconds and then the etched site is washed for 40 seconds (15) and then the bonding procedures are performed according to the instructions of the bonding material manufacturer for the premolars on both sides of the maxilla. Patients are evaluated for 12 months with one-month follow-up periods for bracket bond failure on either side.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthodontic private office of Dr.Maziar Esmailimoghaddam
Full name of responsible person
Maziar Esmaili Moghaddam
Street address
Khanbabakhan St. Andisheh Building 2
City
Orumieh
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3225 4777
Email
maziaremoghaddam@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Alborz st
City
Orumieh
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3336 3590
Email
mohebbi_iraj@yahoo.co.uk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iraj Mohebbi
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
Oroumia University of Medical Sciences
Full name of responsible person
Hatef Mohammadi
Position
Dentistry student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Uorjans Alley, Resalat Boulevard
City
Orumieh
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3336 3590
Email
hatefm7677@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Maziar Esmaili Moghadam
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Uorjans Alley, Resalat Boulevard
City
Orumieh
Province

West Azarbaijan

Postal code
5714783734

Phone
+98 44 3336 3590

Email
maziaremoghaddam@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Hatef Mohammadi

Position
Dentistry student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
Uorjans Alley, Resalat Boulevard

City
Orumieh

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3336 3590

Email
hatefm7677@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentifiyng individuals

When the data will become available and for how long
6 months after printing the results

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

Under which criteria data/document could be used
There are no condition.

From where data/document is obtainable
By email or phone number

What processes are involved for a request to access data/document
After requesting to receive the data, the data will be available to the person one week later.

Comments