

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of home and office bleaching methods on the shear bond strength of metal brackets

Protocol summary

Study aim

Effect of home and office bleaching methods on the shear bond strength of metal brackets

Design

A clinical trial with 3 parallel groups with different interventions, single-blind, randomized, phase 2 is performed on 175 randomized teeth using Random allocation software.

Settings and conduct

Among the patients referred to the specialized department of Tabriz Dental School who need extraction of premolars in the orthodontic treatment process, participate in the study. Patients are randomly divided into three groups. In the home bleaching group, 20% carbamide peroxide will be used for three hours a day for 8 days, and in the office bleaching group, 45% hydrogen peroxide will be used for three days and half an hour a day. After bleaching, both intervention groups are divided into 3 subgroups (n = 25). In the first subgroup 24 hours, in the second 1 week, and in the third 15 days after bleaching the brackets are bonded to the tooth surface and after 30 days the teeth are extracted. The shear bond strength will be measured. In control, no bleaching process will be performed. The evaluator is not aware of the type and timing of teeth bleaching.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients whose mesiodistal width of the premolars is similar and approximately 7-8 mm Exclusion criteria: Has congenital anomalies and structural defects in the premolars

Intervention groups

Group A: They are treated in the office before bleaching the brackets Group B: Before bonding the brackets are treated at home bleaching Control group: Do not undergo bleaching before bonding brackets

Main outcome variables

Shear bond strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220519054918N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Sattar Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 974 0206

Email address

akbarisattar2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-23, 1401/03/02

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of home and office bleaching methods on the shear bond strength of metal brackets

Public title

Investigation of the effect of home and office bleaching on the strength of orthodontic metal brackets

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Orthodontic patients whose treatment plan includes premolar extraction Patients in the age group of 15-35 years Patients without hypoplasia or severe wear on premolar teeth Patients without restoration or caries in premolar teeth Patients who have not previously used chemicals such as hydrogen peroxide for bleaching or other treatments

Exclusion criteria:

Patients with congenital anomalies and structural defects in premolars Patients with dental allergies

Age

From **15 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **175**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is simple and its unit is individual. Randomization tools include the use of random number tables with random allocation. Participants are randomly assigned to one of the groups. Assignment of treatment to patients will also be done randomly. In this way, the type of treatment with the code A (bleaching in the clinic), B (home bleaching), and C (control) is specified and the patient will be given the treatment using a random number table with random allocation. None of the patients is informed of the other patient's treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding in the shear bond strength assessment stage should be done for the person measuring the bond strength, which will be done by coding the studied groups. Recognize from evaluation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.157

Health conditions studied**1****Description of health condition studied**

Dental anomalies

ICD-10 code

Z46.4

ICD-10 code description

Encounter for fitting and adjustment of orthodontic device

Primary outcomes**1****Description**

Shear bond strength

Timepoint

30 days after bleaching

Method of measurement

Materials testing machine

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In group A patients, the bleaching process will be performed in the office with carbamide peroxide (Opalescence Quick PF 45% kit, Ultradent, USA). In this way, 45% hydrogen peroxide will be placed on the teeth for three days and half an hour a day according to the factory instructions.

Category

Treatment - Other

2

Description

Intervention group: In group B patients, the bleaching process will be performed at home with carbamide peroxide (Opalescence PF 20%, Ultradent, USA). Thus, 20% carbamide peroxide will be placed on the teeth 8 hours a day for 8 days.

Category

Treatment - Other

3

Description

Control group: Control group: In patients in the control group, no bleaching process will be performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental School

Full name of responsible person

Behnam Mirza Kouchaki

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Tabriz University of Medical Sciences, Golgasht St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Kachuei

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sattar Akbari

Position

Orthodontic Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Sattar Akbari

Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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