

# 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

**Street address**

Tabriz University of Medical Sciences, Golgasht St.

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akbarisattar2@gmail.com

## 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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Tabriz University of Medical Sciences, Golgasht St

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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

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Orthodontic Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
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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