

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative assessment of Streptococcus mutans population between conventional composites and composites containing bioactive glass in fixed orthodontic patients

Protocol summary

Study aim

Comparison of Streptococcus mutans bacteria accumulation around orthodontic brackets between two groups of conventional composite and composite containing BAG in fixed orthodontic patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 24 patients with 2 samples per patient. For randomization, control and test sides are selected by coin toss.

Settings and conduct

This study will be conducted in the orthodontic department of the Dentistry Faculty of Kerman University of Medical Sciences. In each patient, the control and test sides are randomly selected by tossing a coin. The operator who performs the bracket bonding is blinded to the study, so they do not know which side the brackets are bonded with which composite. At this stage, a code is given to each side of the participants' mouth. Patients are also blinded to the study. For microbial investigation, sampling is done by another operator who is unaware of the side where the brackets are bonded with each composite. This operator presents their reports using the study coding system.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need fixed orthodontic treatment; Patients whose upper second premolar teeth are without macroscopic cracks, caries or enamel hypoplasia; Patients who do not have any dental caries. Exclusion criteria: Patients with systemic diseases; Patients with drug-related xerostomia; Patients with periodontal diseases; Patients whose upper second premolar bracket is detached during treatment.

Intervention groups

Intervention group: Bracket bonding using composite containing BAG (TransbondXT adhesive containing BAG)
Control group: Bracket bonding using conventional

composite (TransbondXT adhesive)

Main outcome variables

Accumulation of Streptococcus mutans around the brackets of upper premolar teeth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220912055949N1**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Sahar Zolfigol

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative assessment of Streptococcus mutans population between conventional composites and composites containing bioactive glass in fixed orthodontic patients

Public title
A comparative assessment of Streptococcus mutans population between conventional composites and composites containing bioactive glass in fixed orthodontic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who need fixed orthodontic treatment. Patients whose upper second premolar teeth are without macroscopic cracks, caries or enamel hypoplasia. Patients who do not have any dental caries.
Exclusion criteria:
Patients with systemic diseases Patients with drug-related xerostomia Patients with periodontal diseases Patients whose upper second premolar bracket is detached during treatment.

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each patient in the upper jaw and premolar region, both control and test sides are randomly selected by tossing a coin. (allocation ratio 1:1)To prepare the tooth enamel, 37% phosphoric acid gel is placed on the tooth enamel for 30 seconds and then washed for 30 seconds and dried for 20 seconds. On the control side, after preparing the tooth enamel, a thin layer of liquid primer (Transbond XT) is placed on the surface of the tooth and the adhesive (TransbondXT) is immediately used to bond the bracket. On the test side, TransbondXt containing BAG is used as an adhesive.

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, in each patient, both control and test

sides are randomly selected by tossing a coin. (allocation ratio 1:1) To prepare the tooth enamel, 37% phosphoric acid gel is placed on the tooth enamel for 30 seconds and then washed for 30 seconds and dried for 20 seconds. On the control side, after preparing the tooth enamel, a thin layer of liquid primer (Transbond XT) is placed on the surface of the tooth and the adhesive (TransbondXT) is immediately used to bond the bracket. On the test side, TransbondXt containing BAG is used as an adhesive.

Blinding (investigator's opinion)

Double blinded

Blinding description

The operator who performs the bracket bonding is blinded to the study, so he does not know which side the brackets are bonded with which composite. At this stage, a code is given to each side of the participants' mouth. Patients are also blinded to the study. For microbial investigation, sampling is done by another operator who is unaware of the side where the brackets are bonded with each composite. This operator presents his reports using the study coding system.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Haft Bagh Alavi axis, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-11-07, 1401/08/16

Ethics committee reference number

IR.KMU.REC.1401.362

Health conditions studied

1

Description of health condition studied

Streptococcus mutans accumulation around dental brackets

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Composite containing bioactive glass

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Accumulation of Streptococcus mutans around the brackets of upper premolar teeth

Timepoint

At the beginning of the study (before the start of the intervention), 3 and 6 months after the bonding of brackets

Method of measurement

Sampling is done using a sterile swab. The swab is transferred to a micro tube containing 200 microliters of sterile phosphate buffer. The micro tube is immediately transferred to the microbiology laboratory at a temperature of 4 degrees Celsius. 100 microliters of each sample is cultured on Mitis salivarius agar culture medium. In this study, glycosyl transferase-1 (gtfb-1) gene sequence will be used and with the help of this technique, the amount of Streptococcus mutans accumulation will be measured and compared.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bracket bonding using composite containing BAG (TransbondXT adhesive containing BAG)

Category

Treatment - Other

2

Description

Control group: Bracket bonding using conventional composite (TransbondXT adhesive)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry Faculty of Kerman University of Medical Sciences

Full name of responsible person

Sahar Zolfigol

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Dentistry Faculty of Kerman University Medical Sciences, Shafa St., Jomhour Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Moluk Torabi Parizi

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Sahar Zolfigol

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

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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