

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

In vivo comparison between the effect of GC composite without primer and conventional composite on white spot lesion around orthodontic brackets : A randomized clinical trial

Protocol summary

Study aim

impact assessment of GC without primer composite on white spot lesion around orthodontic brackets

Design

Randomized clinical trial with parallel control group, double blind, randomized according to file number sequence , at 9 mounts with 2 recalls

Settings and conduct

research occur in tehran azad dental university and 2 private office in tehran. A split-mouth clinical trial study was performed on the lateral and premolar teeth of 50 patients. After etching and drying the Control quadrant we applied primer on the etched surface then we applied Transbond XT composite and brackets. In the opposite quadrant (case group) we did not apply primer after etching and drying and then we applied GC composite without primer with brackets on the tooth surface. After 6 and 9 months of treatment, we evaluated the caries with 2 dental student without knowing about bonding formation for assessment of WSL with ICDAS II index

Participants/Inclusion and exclusion criteria

all patient that visited at azad dental university and two private office in tehran in 1397 1. similar crowding of lateral and first pre molar 2. 3mm or more distance between brackets and gingiva 4. lateral and first pre molar without wsl , caries , retoration , crown 5. without smoking 6. no systemic disease and drugs that occur xerostomia

Intervention groups

one quadrant of maxilla and mandible that bond with gc without primer composite were case group and the other quadrant that bond with transbond xt composite were control groups.

Main outcome variables

WSL occur

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181027041476N1**

Registration date: **2019-10-06, 1398/07/14**

Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**

Update count: **0**

Registration date

2019-10-06, 1398/07/14

Registrant information

Name

Elmira Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2204 2304

Email address

e_asadi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-14, 1397/07/22

Expected recruitment end date

2018-11-13, 1397/08/22

Actual recruitment start date

2018-10-14, 1397/07/22

Actual recruitment end date

2018-11-13, 1397/08/22

Trial completion date

2019-08-13, 1398/05/22

Scientific title

In vivo comparison between the effect of GC composite without primer and conventional composite on white spot lesion around orthodontic brackets : A randomized clinical trial

Public title

In vivo comparison between the effect of GC composite without primer and conventional composite on white spot lesion around orthodontic brackets : A randomized clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

similar crowding in lateral and first pre molar in each arch 3 mm or more distance between brackets and gingiva without history of fixed orthodontic treatment no wsl, caries, crowns and restoration in lateral and first pre molar

Exclusion criteria:

smoking without systemic disease and drugs that occur xerostomia history of fixed orthodontic treatment

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **8**

in each patient one quadrant in maxilla and the opposite site quadrant of mandible are bond with gc without primer composite and the other side of mandible and maxilla are bond with Transbond XT composite.

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **8**

in each patient one quadrant in maxilla and the opposite site quadrant of mandible are bond with gc without primer composite and the other side of mandible and maxilla are bond with Transbond XT composite.

Randomization (investigator's opinion)

Randomized

Randomization description

selection of patients is based on sequence number of files. Odd numbers were given to right side of maxilla and left side of mandible and even numbers were given to left side of maxilla and right side of mandible were case group

Blinding (investigator's opinion)

Double blinded

Blinding description

bonding info and groups record by dentist but patient and 2 dental student assessor dont know this information.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran Azad University of Medical Sciences

Street address

NO 9 , neiestan 9 , pasdaran

City

tehran

Province

Tehran

Postal code

1946853314

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.013

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

Caries , White spot lesion

ICD-10 code

K02

ICD-10 code description

Dental caries

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

white spot lesion

Timepoint

6 and 9 months after bonding

Method of measurement

with ICDAS 2 Criteria , use ball end explorer

Secondary outcomes

empty

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

Intervention group: first clean buccal surface with pumice powder and prophylactic cap to remove plaques. then etch buccal surface with phosphoric acid 37% (Reliance , Itasca , III) for 20 seconds and then rinse it with water and dry it up to rise a chalky white appearance. Then According to the manufacturer's brochure, we dont put primer and only put GC without primer composite (GC Ortho Connect 90-1100-000) with bracket on the dental surface with light pressure and remove the extras with a scaler, then cure for 20 seconds (10s mesial and 10s distal).

Category

Prevention

2

Description

Control group: first clean buccal surface with pumice powder and prophylactic cap to remove plaques. then etch buccal surface with phosphoric acid 37% (Reliance , Itasca , III) for 20 seconds and then rinse it with water and dry it up to rise a chalky white appearance. Then we put primer and cure for 20 seconds and then put Transbond XT composite with bracket on the dental surface with light pressure and remove the extras with a scaler, then cure for 20 seconds (10s mesial and 10s distal).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Azad University Dental branch

Full name of responsible person

Elmira Asadi

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Web page address

http://dental.iautmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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drarashazizi@yahoo.com

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Elmira Asadi

Position

Associate professor

Latest degree

Specialist

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

Elmira Asadi

Position

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Latest degree

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Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Elmira Asadi

Position

Associate professor

Latest degree

Specialist