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)
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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 , lll) 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 , lll) 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

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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