

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Shear bond strength of brackets and enamel demineralization around brackets bonded with self etching primers compared to conventional acid etch technique: An in-vivo study

Protocol summary

Summary

The aim of this study is to compare the effect of conventional acid etch technique and self etching primers on shear bond strength and demineralization around brackets. The statistical population comprises of patients referring to Hamadan dental school and private office of Doctor Farhadian for fixed orthodontic treatment. Twenty five patients with no craniofacial anomaly and systemic disease who require at least two sound intact premolar extraction are selected as the sample size. The orthodontic brackets are bonded randomly with conventional Acid etch technique (Controls) on one side and with Self Etching Primer (Experimental group) on the opposite side. A vertical loop formed with a 0.014 inch Stainless Steel wire is tied in the brackets with elastomeric module to help accumulate plaque. The teeth having the mentioned brackets are extracted at least 8 to 9 weeks later. Then, shear bond strength of brackets and demineralization around brackets are registered as the primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705099086N3**

Registration date: **2017-07-07, 1396/04/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-07, 1396/04/16

Registrant information

Name

Nasrin Farhadian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1835 4017

Email address

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-07-08, 1396/04/17

Expected recruitment end date

2017-11-08, 1396/08/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Shear bond strength of brackets and enamel demineralization around brackets bonded with self etching primers compared to conventional acid etch technique: An in-vivo study

Public title

Comparison of the effect of type of orthodontic bracket adhesive on dental caries around brackets and bond strength

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients requiring fixed orthodontic

treatment for upper and/or lower arch; Treatment plan based on at least 2 premolar extraction; No previous orthodontic treatment; Sound and intact enamel on the buccal area; No restoration, attrition, and caries on enamel Exclusion criteria: Craniofacial anomalies; Hypoplasia and obvious demineralization of enamel; Systemic diseases

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

committee of ethics in research

Street address

Hamadan University of Medical Sciences

City

Hamadan

Postal code

Approval date

2017-05-27, 1396/03/06

Ethics committee reference number

IR.UMSHA.REC.1396.166

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel

Primary outcomes

1

Description

Enamel demineralization around brackets

Timepoint

8-9 weeks after treatment

Method of measurement

Lesion depth in microns by polarized light microscopy

2

Description

Shear Bond Strength

Timepoint

8-9 weeks after treatment

Method of measurement

pressure in megapascal by Instron universal testing machine

Secondary outcomes

1

Description

Adhesive Remnant Index

Timepoint

8-9 weeks after treatment

Method of measurement

stereomicroscope with magnification by 60 times

Intervention groups

1

Description

Intervention: This group will receive Self Etching Primer for bonding brackets and after at least two months, the teeth were examined for demineralization and shear bond strength.

Category

Prevention

2

Description

Control: This group will receive conventional Acid Etch technique for bonding brackets and after at least two months, the teeth were examined for demineralization and shear bond strength the same as the intervention group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, Dental School, Hamadan

University of Medical Sciences
Full name of responsible person
Street address
City
Hamadan

2

Recruitment center
Name of recruitment center
Office of Dr. Nasrin Farhadian
Full name of responsible person
Street address
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology, Hamadan
University of Medical Sciences
Full name of responsible person
Saeid Bashirian
Street address
Shahid Fahmideh Street
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology, Hamadan
University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty