

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Clinical comparison of preventive resin restoration retention using Nano-bonding and Etch-&-Rinse Adhesive systems (Conventional method)

Protocol summary

Study aim

The objective of this study was clinical comparison of the retention of preventive resin restoration using Nano-bonding and Etch-&-Rinse Adhesive systems (Conventional method)

Design

In this study, 42 patients in the age group of 6-12 years were randomly selected by rand list software who had permanent molars with occlusal surfaces decay at the 2-sided mandibular molar and qualified for I-type preventive resin restoration . Then , patients were non-randomly divided in two control and control and intervention groups . Clinical-trial phase is not exemplified in this study .

Settings and conduct

This clinical trial study on prevention of decay progress will be done in Tabriz Dentistry Faculty . the samples will be 42 individuals in the age group of 6-12 years . In each sample , a tooth will be treated by preparation method with Nano-bonding and the same tooth in the opposite side will be treated with the conventional method (etching acid and bonding) .

Participants/Inclusion and exclusion criteria

The criteria for entering the study are: group of 6-12 years of age - presence of permanent teeth of the first molar in the lower jaw on both sides, with minor decay at the occlusal level - evidence of oral hygiene at home - patient collaboration and acceptance of treatment - no therapeutic treatment has been performed on the teeth previously - possibility of isolation by cotton roll and suction. Exit criteria: history of medical illness that may interfere with treatment, drug affecting the saliva and its quality, history of allergy to any of the restorative materials - un cooperation of patient .

Intervention groups

Intervention group : preventive resin restoration therapy with Nano-bonding in a molar tooth in one quadrant of the mandible control group : preventive resin restoration therapy with conventional method (Etch-&-Rinse

Adhesive systems)

Main outcome variables

Retention of preventive resin restoration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100125003168N4**

Registration date: **2017-12-18, 1396/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-18, 1396/09/27**

Update count: **0**

Registration date

2017-12-18, 1396/09/27

Registrant information

Name

Leila Erfanparast

Name of organization / entity

Tabriz University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice-Chancellor, Tabriz University of Medical Sciences

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Clinical comparison of preventive resin restoration retention using Nano-bonding and Etch-&-Rinse Adhesive systems (Conventional method)

Public title

The clinical comparison of two methods for preventive resin restoration of young permanent teeth

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

group of 6-12 years of age presence of permanent teeth of the first molar in the lower jaw on both sides with minor decay at the occlusal level evidence of oral hygiene at home patient collaboration and acceptance of treatment no therapeutic treatment has been performed on the teeth previously possibility of isolation by cotton roll and suction

Exclusion criteria:

history of medical illness that may interfere with treatment drug affecting the saliva and its quality history of allergy to any of the restorative materials uncooperation patient

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

two first molar teeth with partial carious lesions at the occlusal level were in the lower jaw

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research vice-chancellor, Tabriz University of Medical Sciences

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Daneshgah Ave. - Golgasht St.-Tabriz University of Medical Sciences

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tabriz

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Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.TBZMED.REC.1396.642

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

dental caries

ICD-10 code

k02.0

ICD-10 code description

بوسیدگی های دندانی محدود به مینا

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

The retention of restoration

Timepoint

3 and 6 months

Method of measurement

exploration and observation

Secondary outcomes**1****Description**

The working time

Timepoint

3 and 6 months

Method of measurement

exploration and observation

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

intervention group : 1)tooth cleaning2)remove

caries3)isolation4)using Nano-bonding (G-premi Bond,GC Corporation,Tokyo,Japan) and cure for 20 seconds5)use of sealant (Clinpro-3M,USA) and cure for 20 seconds6)evaluation of occlusion and do finish and polish

Category

Prevention

2**Description**

Control group: 1)tooth cleaning2)remove caries3)isolation4)using 37% acid etch (Etch Rite , PULPDENT Corporation , USA)for 20 seconds then , Rinse acid for 20 seconds 5)use of bonding (single bond 2, 3M ESPE, PULPDENT Corporation ,U.S.A) and cure for 15 seconds 6)use of sealant (Clinpro-3M,USA) and cure for 20 seconds7) evaluation of occlusion and do finish and polish

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Faculty of Dentistry-Department of Pediatric Dentistry

Full name of responsible person

leila Erfanparast

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Reasearch Vice-Chancellor- Tabriz University of Medical Sciences

Full name of responsible person

mohammad samiei

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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

Reasearch Vice-Chancellor- 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**

faculty of dentistry

Full name of responsible person

leila Erfanparast

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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