Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical comparaison of the retention of fissure sealant following preparation with seventh generation bonding agent with separate etch and preparation with etch and rinse(fifth generation

Protocol summary

Study aim

The objective of this study was clinical comparaison of the retention of fissure sealant following preparation with seventh generation bonding agent with separate etch and preparation with etch and rinse(fifth generation).

Design

The samples will be 40 individuals in the age group of 7-12 years randomly selected by randlist software, in which they have a pair of first permanent healthy molars without 2-sided mandibular molars decay with condition of fissure sealant therapy. Then, patients were non-randomly divided in two control and intervention groups. Clinical-trial phase is not exemplified in this study.

Settings and conduct

This clinical trial study on decay prevention will be done in Tabriz Dentistry Faculty. the samples will be 40 individuals in the age group of 7-12 years . In each sample, a tooth will be treated by preparation method with a seventh-generation bonding method plus a separate etch and the same tooth in the opposite side will be treated with the usual preparation method (etching acid with bonding) with fifth generation of sealant.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1)7-12 years of age,2)presence of two first lower molars without caries, 3)deep groove that indicate fissure sealant therapy,4)satisfaction of parentes. Exclusion Criteria 1) carious molars, 2)if two molars were not in the same jaw

Intervention groups

Intervention group: fissure sealant therapy with Clearfil S3 Bond and separate etch in a molar tooth in one quadrant of the mandible Control group: fissure sealant therapy with acid etch and bonding in the molar of the opposite side of the intervention group

Main outcome variables

Retention of fissure sealant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171107037300N1**
Registration date: **2017-12-04, 1396/09/13**
Registration timing: **prospective**

Last update: **2017-12-04, 1396/09/13**
Update count: **0**

Registration date

2017-12-04, 1396/09/13

Registrant information

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Azin Sohrabi

Name of organization / entity
Faculty of Dentistry

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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

Clinical comparaison of the retention of fissure sealant following preparation with seventh generation bonding agent with separate etch and preparation with etch and rinse(fifth generation

Public title

The clinical comparison of two methods for sealing fissures of young permanent teeth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

7-12 years of age presence of two first lower molars without caries deep groove that indicate fissure sealant therapy satisfaction of parentes

Exclusion criteria:

carious molars if two molars were not in the same jaw

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

two intact first molars 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

Street address

Daneshgah Ave-Golgasht St.- Faculty of Dentistry-Department of Pediatric Dentistry

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Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.TBZMED.REC.1396.648

Health conditions studied

1

Description of health condition studied

clinical evaluation of two fissure sealant therapy methods

ICD-10 code

z01.2

ICD-10 code description

dental examination

Primary outcomes

1

Description

The retention of sealants

Timepoint

6 months

Method of measurement

exploration and observation

Secondary outcomes

1

Description

The working time

Timepoint

6 months

Method of measurement

exploration and observation

Intervention groups

1

Description

Intervention group:1)Isolation 2)Tooth cleaning 3)Using 37% acid etch(Etch Rite,PULPDENT Corporation U.S.A) for 15 seconds 4)Rinse acid for 15 seconds 5)Use of bonding(Clearfil S3 Bond ,3M ESPE-PULPDENT Corporation U. S.A) on tooth surface and curing for 10 seconds 6)Use of sealant(Clinpro-3M, U.S.A) on tooth surface and curing for 20 seconds 7) evaluation of sealing groove and occlusion

Category

Prevention

2

Description
Control group: 1)Isolation 2)Tooth cleaning 3)Using 37% acid etch(Etch Rite,PULPDENT Corporation U.S.A) for 15 seconds 4)Rinse acid for 15 seconds 5)Use of bonding(Single Bond2 ,3M ESPE-PULPDENT Corporation U. S.A) on tooth surface and curing for 10 seconds 6)Use of sealant(Clinpro-3M, U.S.A) on tooth surface and curing for 20 seconds 7) evaluation of sealing groove and occlusion

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Faculty of Dentistry-Department of Pediatric Dentistry

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
Dr Azin sohrabi

Position
Asistant Proffessor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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