

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical comparison of retention, caries and marginal integrity of a self etching fissure sealant to conventional sealant:12 months follow up

Protocol summary

Summary

Objective: The objective of this study is to compare a self-etching sealant with a conventional fissure sealant over 3, 6 and 12 months follow up. Study designing: double blinded randomized clinical trial Methods: in this clinical trial, sample group consisted of 200 first permanent molars teeth of 50 children aged 7 to 9 years. Selection criteria include four fully erupted first permanent molars in each patient and the permanent molars have deep, narrow and retentive fissures. The first permanent molars with occlusal or approximal caries and Patients with any bruxism or malocclusion are exclusion criteria. A split mouth technique, where the two techniques will be randomly allocated to either the right or the left side of the mouth is used. On the one side, a self-etching light cured fissure sealant, Prevent Seal (Itena, Paris, France) and on the other side, a conventional light-cured fissure sealant concise (3M ESPE, St. Paul, MN, USA) will be used. At the follow-up visits after 3 and 6 months the sealants will be evaluated in terms of retention, the presence of caries and marginal integrity according to Modified USPHS system and two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110157800N1**

Registration date: **2011-12-17, 1390/09/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-17, 1390/09/26

Registrant information

Name

Morteza Saleki

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Dental Research, School of Dentistry, Azad University, Khorasgan branch, Isfahan, Iran Dr. Morteza Saleki

Expected recruitment start date

2011-11-13, 1390/08/22

Expected recruitment end date

2011-11-17, 1390/08/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison of retention, caries and marginal integrity of a self etching fissure sealant to conventional sealant:12 months follow up

Public title

effect of sealing teeth with self etching fissure sealant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a) four fully erupted first permanent molars in each patient b) first permanent molars with deep, retentive and sound fissures c) without any caries

in other teeth d)doing oral hygiene methods by the patients exclusion criteria: a)first permanent molars with occlusal or proximal caries b)Patients with any bruxism or malocclusion c)semi erupted first permanent molars

Age

From **7 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Azad University Khorasgan branch, Isfahan, Iran.

Street address

School of dentistry, Azad University Khorasgan branch, Arghavaniye Boulevard, khurasgan

City

Khurasgan

Postal code

Approval date

2011-07-02, 1390/04/11

Ethics committee reference number

23810201892036

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes

1

Description

fissure sealant retention

Timepoint

3 , 6 and 12 months

Method of measurement

Modified USPHS

2

Description

incipient caries

Timepoint

3, 6 and12 months

Method of measurement

Modified USPHS

3

Description

marginal integrity of fissure sealant

Timepoint

3 , 6and 12 months

Method of measurement

Modified USPHS

Secondary outcomes

1

Description

fissure sealant porosity

Timepoint

3 , 6 and12 months

Method of measurement

Modified USPHS

Intervention groups

1

Description

Intervention:Self etching fissure sealant, Prevent seal: after cleaning the tooth surface,fissure sealant is allocated without any etching and rinsing.

Category

Treatment - Other

2

Description

Control:conventional fissure sealant:3M:before sealant placement,doing etching and rinsing for 15 and 20 seconds,respectively.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhangian Dental clinic

Full name of responsible person

Dr. Morteza Saleki, Post graduate student of pediatric dentistry

Street address**City**

Shahreza

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Dental Research, School of Dentistry, Azad University, Khorasgan branch

Full name of responsible person

Dr. Vahid Esfahanian

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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

Deputy of Dental Research, School of Dentistry, Azad University, Khorasgan branch

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>