

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

One year clinical evaluation of glass ionomer and resin based fissure sealants on permanent first molars

Protocol summary

Summary

Introduction: salivary contamination is the major cause of sealants' loss in the first year. Despite the resin base sealants being considered as the first choice in sealant therapy, recent advances in the production of glass-ionomers, these materials have been proposed as a viable option for sealant therapy. The aim of this study was to evaluate the 12 month clinical success rate of two types of resin and glass ionomer sealant. Method : Samples for randomized clinical trial study consist of 40 children 6-10 years that meet inclusion criteria. 2 first molars in one jaw will be sealed randomly.one side with resin based sealant (Heliocell) and the other side with glass ionomer sealant (fuji triage).Sealants will be evaluated after 3, 6,9 and 12 months using modified Ryge criteria for retention, marginal adaptation, colour match, surface smoothness and caries.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041611960N2**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Nasim Shafieezadeh

Name of organization / entity

Islamic Azad University, Dental branch

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-22, 1393/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

One year clinical evaluation of glass ionomer and resin based fissure sealants on permanent first molars

Public title

Clinical evaluation of Glass Ionomer fissure sealants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children 6 to 10 from both sex whom are admitted in pediatric department of dental branch.They should have 2 first permanent fully erupted intact molars in one jaw without any previous treatment .They should be behaviorally manageable, without any systemic disorder or consuming any drug with saliva effect; at least dmft index =1 and O'Leary index:10%.

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

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

Dental Branch, Islamic Azad University

Street address

No5 ,Neyestan 10, Pasdaran Ave

City

Tehran

Postal code

19585/175

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

پ/150/د

Health conditions studied

1

Description of health condition studied

Dental caries prevention

ICD-10 code

Y56.7

ICD-10 code description

Dental drugs, topically applied

Primary outcomes

1

Description

Sealant retention

Timepoint

At months: 3, 6, 9 and 12

Method of measurement

Clinical examination

2

Description

Marginal adaptation

Timepoint

At months: 3, 6, 9 and 12

Method of measurement

Clinical examination

3

Description

Color adjustment

Timepoint

At months: 3, 6, 9 and 12

Method of measurement

Clinical examination

4

Description

Surface smoothness

Timepoint

At months: 3, 6, 9 and 12

Method of measurement

Clinical examination

5

Description

Caries

Timepoint

At months: 3, 6, 9 and 12

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

In one jaw, one side permanent molar will be sealed with glass inomer material fissure sealant: Fuji Triage triage (GC, Tokyo, Japan) (case group)

Category

Prevention

2

Description

The first permanent molar in the other side of the same jaw will be sealed with resin based material fissure sealant: Heliobond-F (Ivoclar Vivadent AG, Schaan, Liechtenstein) (control group)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Branch, Islamic Azad University

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Branch, Islamic Azad University

Full name of responsible person

Dr Marjan Azarshab

Street address

No 5, Neyestan 10, Pasdaran Ave

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Dental Branch, Islamic Azad University

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**

Dental Branch, Islamic Azad University

Full name of responsible person

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Assistant Professor/Pedodontist

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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

