Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 (HelioselF) 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 Shafiezadeh

Name of organization / entity

Islamic Azad University, Dental branch

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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 Oleary 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 examinatioin

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 salant: 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: Helioseal-F(ivoclar vivadent AG, schoan, 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
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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
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Person responsible for updating data

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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*