Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Clinical evaluation of posterior resin composite and glass ionomer cement restorations in primary molars

Protocol summary

Summary

1. Objective of the study: clinical comparison of a posterior composite and an inomer glass cement pack for primary tooth restoration 2. Study design: random, single blind, 2 trial phase 3. Methodology: after the patients are selected based on inclusion criteria, the method is as follows: Occlusal surface caries are removed by high-speed handpiece with water spray. This is done with minimal removal of healthy dental structure. After caries removal, the cavity is washed and dried. Moisture is controlled by cotton roll and strong saliva suction. According to manufacturers, for the second mandibular primary molar of one side is randomly washed with moist cotton ball and then dried by clean cotton ball. Then, Fuji IX Gp Extra glass inomer cement (EQUIA) is placed and covered by Vaseline to protect from contamination and moisture. And on the other side, the cavity is etched by phosphoric acid gel 35%. The cavities are fully washed by water and air spray and mildly dried by air syringe. After the cavity is etched, a single bond agent is applied with slow movement of applicator tip and is attenuated by air flow. Curing the bond agent is performed by LED light cure machine and then M3 compressable posterior composite is placed into the cavity and is lightly cured. Then, every tooth is investigated by dental mirror and probe for lack of bubbles, marginal adaptation and polymerization completion; and if any problem is observed, the tooth is re-treated. Then the occlusion is investigated using articulation paper. If any early contacts are observed, the points of interestare removed by milling process.After treatment completion, standard preventive methods, including nutritional recommendations, health education and using topical Fluoride, are explained orally and in a written manner. Then avery restored tooth is evaluated in 6, 12 and 18 month intervals by dental mirror and probe; and according to USPHS index, marginal integrity, color match, marginal spot, anatomic form and secondary caries are recorded. It must be noted that all above-mentioned treatment stages are performed by one and the same person (professional pediatric dentistry assistant). Statistical Chi-square tests are then applied to evaluate the obtained results. 4. Participants: 50 children aged 4-9 years old having small to moderate caries lesions on occlusal surface of the second mandibular primary molar are selected. a) Major inclusion criteria: presence of small to medium caries on occlusal surface of the second primary molar on both right and left of mandible; presence of proximal contact with the adjacent intact or restored tooth; lack of any indications for pulp therapy or other restrorative treatments on the studied teeth; lack of involvement of periodontal tissues; at least two years left to normal tooth loss b)Major exclusion criteria: extensive caries lesions, children younger than 4 and older than 9 years old 5. Interventions: M3 posterior composite of Fuji IX glass inomer cement pack 6. primary implication: dental caries.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092019234N1**
Registration date: **2015-03-23, 1394/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-03-23, 1394/01/03

Registrant information

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Name of organization / entity

Islamic Azad University Isfahan Branch

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Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2013-03-20, 1391/12/30
Expected recruitment end date
2015-02-19, 1393/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of posterior resin composite and glass ionomer cement restorations in primary molars

Public title
Clinical evaluation of posterior resin composite and glass ionomer cement restorations in primary molars:18-month follow up.
Purpose
Treatment
Inclusion/Exclusion criteria
Major inclusion criteria: presence of small to medium caries on occlusal surface of the second primary molar on both right and left of mandible; presence of proximal contact with the adjacent intact or restored tooth; lack of any indications for pulp therapy or other restrorative treatments on the studied teeth; lack of involvement of periodontal tissues; at least two years left to normal tooth loss Major exclusion criteria: extensive caries lesions;children younger than 4 and older than 9 years old
Age
From **4 years** old to **9 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University Isfahan Branch(Khorasgan)
Street address
Dental School, Islamic Azad University Isfahan(Khorasgan), J stree
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Postal code
81551-39998
Approval date
2014-01-25, 1392/11/05
Ethics committee reference number
493027

Health conditions studied

1

Description of health condition studied
Dental Caries
ICD-10 code
k02
ICD-10 code description
dental caries

Primary outcomes

1

Description
Dental Caries
Timepoint
6 month-12 month-18 month
Method of measurement
USPHS Criteria

Secondary outcomes

empty

Intervention groups

1

Description
1Intervention:-Glass ionomer cement(EQUIA, Fuji IX GP Extra, GC Dental Co, Tokyo, Japan)
Category
Rehabilitation

2

Description
CONTROL: ESPE FILTEK Z100 DENTAL COMPOSITE UNIVERSAL
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Dr.Maryam Shokri Mozhdehi
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Sponsors / Funding sources

1

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Dental School, Islamic Azad University Isfahan(Khorasgan), J stree
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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
Islamic Azad University Isfahan 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

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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