

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Clinical assessment of using two types of adhesive (PQ1, Prompt-I-pop) on the success rate of fissure sealant with and without saliva contamination

Protocol summary

Summary

Purpose: the effects of two adhesives on the success rate of fissure sealant in the contaminated enamel. inclusion criteria: existing two sound maxillary permanent molar tooth or at least one tooth with remembered characteristics - moderate oral hygiene - no existing systemic disease exclusion criteria: uncooperative patient. In this study; 35 school children (6-8 years of age from Isfahan Jay area) with healthy and newly-erupted upper jaw molar teeth were participated, 60 molar teeth were selected (in the spring 1385) and divided into two groups. For one group, PQ1 and for the other, PROMPT-L-POP was used. As the teeth were newly erupted and the distopalatal area being in contact with the gingival sulcus and so it was impossible to isolate, the distal area was considered as contaminated and the mesial area capable of adequate isolation were assumed isolated. In each group, after etching, in one side, teeth were treated with sealant only and on the other side at first bonding agent was applied and then treated with sealant. So, two control groups were formed for each bonding agent. After 3, 6 and 12-month intervals, the results of the treatment were studied in terms of the success and failure rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903184123N1**

Registration date: **2010-09-08, 1389/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-08, 1389/06/17

Registrant information

Name

Parvin Khadem

Name of organization / entity

Khoorasgan branch of Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 31 1261 5677

Email address

p.khadem@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2006-03-21, 1385/01/01

Expected recruitment end date

2006-04-21, 1385/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical assessment of using two types of adhesive (PQ1, Prompt-I-pop) on the success rate of fissure sealant with and without saliva contamination

Public title

Clinical assessment of using two types of adhesive (PQ1, Prompt-I-pop) on the success rate of fissure sealant with and without saliva contamination

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: existing two sound maxillary permanent molar tooth or at least one tooth with remembered characteristics - moderate oral hygiene - no existing systemic disease exclusion criteria: don't have cooperation of patient

Age

From **6 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

khurasan branch Islamic Azad University

Street address

Argavanieh, Islamic Azad University

City

Isfahan

Postal code

81595-158

Approval date

empty

Ethics committee reference number

23810201862008

Health conditions studied

1

Description of health condition studied

the effect of using bonding on fissure sealant success rate

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Success rate of fissure sealant

Timepoint

3, 6, and 12 month

Method of measurement

Position of fissure sealant (intact, partially failed, completely failed)

Secondary outcomes

1

Description

Decay

Timepoint

3, 6, 12 months

Method of measurement

Oral examination

2

Description

Discoloration

Timepoint

3, 6, 12 months

Method of measurement

Oral examination

Intervention groups

1

Description

intervention 2: use of pq1 bonding; no dose

Category

Treatment - Drugs

2

Description

intervention 1: use of prompt l pop bonding; no dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Community dentistry center of Islamic Azad University

Full name of responsible person

Parvin Khadem

Street address

unit 3, Navid building, Navid alley, Shariati street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khorasgan branch Islamic Azad University

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

Khorasgan 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**

Khorasgan branch of Islamic Azad University

Full name of responsible person

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Position

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Person responsible for updating data

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Parvin Khadem

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address**

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