Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effectiveness of community based Fissure-Sealant therapy in decreasing the level of dental caries in 6-12 years old school children

Protocol summary

Summary

The split-mouth design was employed. In this method, teeth of contrary two quadrants (36–46 and/or 16–26 teeth) were randomly allocated in either the intervention or the control groups. Sample size was 185 school children. The study population consisted of all primary school students (1st and 2nd grade) between the ages of 8 to 10-years-old from the low socio-economic rural areas of Golpayegan city of Isfahan province. The intervention was Fissure sealant treatment carried out by the senior dental students. It was provided as a part of "field program" of Department of Oral Public Health in 2015. Regarding the six codes of ICDAS dental caries, severity for all full-erupted first permanent molars was recorded at baseline. After selection the eligible teeth, the paired teeth were randomly allocated either to the intervention or to the control by previously designed cards After one year the treated teeth were evaluated. An assistant opened the unreadable cards by L as left and R as right signs. The primary outcome of the study was the occurrence of new caries (ICDAS code 3–6) at the 1-year follow-up. The secondary outcome was the sealant's retention status which evaluated as complete retention, partially retention or fully lost after one year. evaluate the effectiveness of the community fissure sealant program by assessing the odds of new caries between the two sealant and control groups. The prevalence of different status of sealant retention is reported too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082229476N1**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellery of Research Affairs , Isfahan University of Medical Sciences

Expected recruitment start date

2015-04-22, 1394/02/02

Expected recruitment end date

2016-05-23, 1395/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of community based Fissure-Sealant therapy in decreasing the level of dental caries in 6-12 years old school children

Public title

effectiveness of Fissure-Sealant therapy in decreasing

the level of dental caries in 6-12 years old school children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: all primary school students (1st and 2nd grade) between the ages of 8 to 10-years-old; low socio-economic rural areas of Golpayegan city of Isfahan province; permanent residents; having at least two sound teeth in two contrary quadrants; teeth with deep sound pit and fissures or primary dental caries (ICDAS 0-2) Exclusion Criteria: no patient cooperation; parents not being eager to participate

Age

From **7 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **185**

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

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hezarjarib ST, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

293220

Health conditions studied

1

Description of health condition studied

Dental Caries

ICD-10 code

K02.0–K02.

ICD-10 code description

Primary outcomes

1

Description

Sealant retention

Timepoint

exactly after treatment, one year after treatment

Method of measurement

Oral Examination

2

Description

Caries Incidence

Timepoint

before the treatment, One year after the treatment

Method of measurement

Oral Examination and ICDAS recording

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The intervention was Fissure sealant treatment carried out by the senior dental students. It was provided as a part of "field program" of Department of Oral Public Health in 2015. Teeth of contrary two quadrants (36–46 and/or 16–26 teeth) were randomly allocated in either the intervention or the control groups. Teeth with deep pit and fissures either healthy or at early stages of enamel decay (ICDAS 0-2) were included in the study and regarding the six codes of ICDAS dental caries, severity for all full-erupted first permanent molars was recorded at baseline. The treatment process included cleaning teeth with low-speed tooth brushing without prophylaxis paste, isolation with cotton rolls and suction, etching with Ultra etch gel (35% phosphoric acid, ultradent Products Inc, USA) for 30 seconds. After thoroughly water rinsing and air drying, applying the bonding agent by Single Bond 2(3M ESPE, USA) and curing, resin-based sealant was applied (Prime-Dent®. Prime Dental manufacturing Inc.3735 W. Belmont Ave. Chicago) to the pit and fissures on the occlusal and buccal surfaces. Using curing light (device LED light cure Woodpecker Medical Instrument Co, China 400-600 mw/cm2) all coated surfaces exposed for 45 seconds. After setting the sealant, teeth were checked by supervisors for retention, air bubbles and occlusal adjustments. If necessary, the processes were repeated

Category
Prevention

2

Description
Control group: The teeth in the contrary quadrant received no treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Red cresent center
Full name of responsible person
Dr Alireza Farzanekhoo
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Golpayegan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellery of Research Affairs
Full name of responsible person
Dr. Omid Savabi
Street address
Hezarjarib st, Isfahan University of Medical Sceinces
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellery of Research Affairs
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
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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