

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the effects that use of fluoride has on clinical success of pit and fissure sealant in children age 6 to 12 years: a clinical trial

Protocol summary

Summary

Aims of this study are the determination of clinical success rate of fissure sealant after using fluoride or without using it on tooth surface and compare these 2 statuses. A method (fissure after fluoride therapy) B method (fissure sealant); in both 2 groups after cleaning the tooth surface by brush and low speed hand piece and washing with water and air pur, Isolation with cotton rolls and suction will be done. In A method, at first, teeth occlusal surface will be put in %1.23 APF gel, then will be washed and dried and etched with %37 acid phosphoric solution. Acid will be washed and dried with water and air pur pressure. After binding and curing that sealant will be putting on created fissure and cure. In B method, all of those procedures except using of fluoride will be done. In both methods, after finishing all process, teeth will be verify in aspects like no bubble, fill conjunction edge, absence of occlusal interferences. Both methods will be done in one session by dentistry student. Then children are examined in 6 month period in aspects of clinical success in 3 ranges like marginal color, full conjunction edge and structural form by 2 clinicians. When fissure sealant will be called successful that have received code 0 or 1 in three ranges.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605163549N8**

Registration date: **2016-12-22, 1395/10/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-22, 1395/10/02

Registrant information

Name

Foroogh Amirabadi

Name of organization / entity

Dental College, Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 9482

Email address

amirabadi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental College of Zahedan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects that use of fluoride has on clinical success of pit and fissure sealant in children age 6 to 12 years: a clinical trial

Public title

Evaluation of the effects that use of fluoride has on clinical success of pit and fissure sealant in children age 6 to 12 years: a clinical trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. The first two molars teeth in

mandible must be fully grown and healthy without any signs of decay, restoration and crack. 2. Proper isolation must be possible. 3. Deep corrugation must be present to show the need for sealant therapy. 4. The patient must be in low risk group and have acceptable dental hygiene. 5. The patient's guardian must complete a form to collaborate with the researches for a period of 6 months. Exclusion criteria: 1. patient who did not accept to participate in this study and will not complete form.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran

City

Zahedan

Postal code

009817699693

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

IR.ZAUMS.REC.1394.356

Health conditions studied

1

Description of health condition studied

Caries after fissure sealant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dental caries

Timepoint

On 6 month after fissure sealant

Method of measurement

Based on observation by probe and mirror under headlight

Secondary outcomes

1

Description

Leakage

Timepoint

On 6 month after fissure sealant

Method of measurement

Based on observation by probe and mirror under headlight

2

Description

Color change

Timepoint

On 6 month after fissure sealant

Method of measurement

Based on observation by probe and mirror under headlight

Intervention groups

1

Description

Fluoride therapy before fissure sealant (Intervention group)

Category

Prevention

2

Description

Fissure sealant (Control group)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatrics Department, Dental College of Zahedan

University of Medical Sciences

Full name of responsible person

Doctor Amirabadi Foroogh

Street address

Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Doctor Rafighdoost Hooshang

Street address

Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

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 College of Zahedan University of Medical Sciences

Full name of responsible person

Aygin Abdali

Position

Dentistry student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Assistant Professor of Pediatric Dentistry Department, Dental College of Zahedan University of Medic

Other areas of specialty/work

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Person responsible for updating data

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Doctor Amirabadi Foroogh

Position

Assistant Professor of Pediatric Dentistry Department, Dental College of Zahedan University of Medic

Other areas of specialty/work

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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