Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 puar, 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 puar 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
Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran
City
Zahedan
Postal code
9817966993
Phone
+98 54 3341 4004
Fax
Email
draysou@icloud.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dental College of Zahedan University of Medical Sciences
Full name of responsible person
Doctor Amirabadi Foroogh
Position
Assistant Professor of Pediatric Dentistry Department, Dental College of Zahedan University of Medic
Other areas of specialty/work
Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran
City
Zahedan
Postal code
9817966993
Phone
+98 54 3341 4004
Fax
Email
amirabadi@zaums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Dental College of Zahedan University of Medical Sciences
Full name of responsible person
Doctor Amirabadi Foroogh
Position
Assistant Professor of Pediatric Dentistry Department, Dental College of Zahedan University of Medic
Other areas of specialty/work
Street address
Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran
City
Zahedan
Postal code
9817966993
Phone
+98 54 3341 4004
Fax
Email
amirabadi@zaums.ac.ir
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