

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of clinical retention of fissure sealants with and without using sodium hypochlorite after enamel etching in 7-12 year old children

Protocol summary

Study aim

Comparison of clinical retention of fissure sealants with and without using sodium hypochlorite after enamel etching.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, on 34 patients. A coin was used for randomization.

Settings and conduct

Samples of 34 people in the age group of 7-12 years will be randomly selected from the patients referred to the pediatric dentistry ward. After examination with a catheter and observation and diagnosis of no caries and the presence of deep grooves, one patient's tooth is treated in the usual way and the other tooth is treated with the researched method. Using a coin, one molar will be randomly selected as the control group and one molar as the intervention group; Therefore, for permanent first molars, one side of the fissure sealant is treated in the usual way and for the first permanent molars on the other side of the mandible after acid etching, sodium hypochlorite is applied and then fissure sealant treatment is performed. And 6 months after treatment, patients will be re-examined. Blinding: The participant will be blind, but due to the nature of the study, the practitioner cannot be blind. Also in the follow-up session, the dentist who is blind to the treatment process will check the sealants.

Participants/Inclusion and exclusion criteria

Presence of any types of dental caries. Medically compromised patients. Tooth isolation impossibility. Lack of cooperation and acceptance from patients or their parents. Self-cleansing occlusal pits and fissures which did not need fissure sealant therapy.

Intervention groups

In the intervention group, after preparation of tooth enamel with acid etching, sodium hypochlorite will be applied and then fissure sealant will be used.

Main outcome variables

Evaluation of the effect of sodium hypochlorite on fissure sealant's retention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210621051650N1**

Registration date: **2021-07-05, 1400/04/14**

Registration timing: **retrospective**

Last update: **2021-07-05, 1400/04/14**

Update count: **0**

Registration date

2021-07-05, 1400/04/14

Registrant information

Name

Masoumeh Vatandoust

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-07-01, 1400/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical retention of fissure sealants with and without using sodium hypochlorite after enamel etching in 7-12 year old children

Public title

Comparison of clinical retention of fissure sealants with and without using sodium hypochlorite after enamel etching

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants should have had cooperation and acceptance for dental treatment and good oral hygiene. Patients with a pair of sound first permanent mandibular molars, bilaterally, which were qualified for fissure sealant therapy. Ages between 7 and 12 years. Teeth should have had acceptable situation for isolation with cotton roll and suction.

Exclusion criteria:

Presence of any types of dental caries. Medically compromised patients. Tooth isolation impossibility. Lack of cooperation and acceptance from patients or their parents. Self-cleansing occlusal pits and fissures which did not need fissure sealant therapy.

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **37**

More than 1 sample in each individual

Number of samples in each individual: **2**

A pair of sound first permanent mandibular molars, bilaterally, which were qualified for fissure sealant therapy.

Randomization (investigator's opinion)

Randomized

Randomization description

Using a coin, one molar will be randomly selected as the control group and one molar as the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant will be blind, but due to the nature of the study, the practitioner cannot be blind. Also in the follow-up session, the dentist who is blind to the treatment process will check the sealants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 45, Golha Alley, North shahriyar Ave, Valiasr Town

City

Tabriz

Province

East Azarbaijan

Postal code

5157838464

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.TBZMED.REC.1400.258

Health conditions studied**1****Description of health condition studied**

Comparison of clinical retention of fissure sealants with and without using sodium hypochlorite after enamel etching

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The percentage of people in whom fissure sealant retention is increased by the use of sodium hypochlorite.

Timepoint

Measurement of fissure sealant retention rate six months after treatment.

Method of measurement

After 6 months, all 34 people will be contacted in order of fissure sealant time and in the pediatric ward of the faculty will be checked by 2 pediatric dentists. The reliability of the examiners will be calculated using Cohen's Kappa statistical coefficient. Each fissure sealant will be evaluated independently using a mirror and a slow catheter after 6 months by 2 calibrated researchers, who were not involved in the treatment process. If there is a disagreement between the two researchers during the evaluation period, after discussion, an agreement will be reached. If the treatment fails, the tooth will be re-treated. The examination technique will be visual observation and clinical evaluation.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Preparation of permanent mandibular first molar enamel with acid etching (usual method) and use of fissure sealant.

Category

Prevention

2

Description

Intervention group: Preparation of enamel with acid etch then apply cotton impregnated with 5.25% sodium hypochlorite and use fissure sealant.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric ward of Tabriz Dental School

Full name of responsible person

Leila Erfanparast

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Golgasht Ave, Daneshgah Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Erfanparast

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Erfanparast

Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data potentially shareable after unidentifiable individuals

When the data will become available and for how long

Access starts six months after the start of the research and the preparation of the preliminary results.

To whom data/document is available

All researchers who are interested in the subject and want to do similar research.

Under which criteria data/document could be used

It can be used to perform similar research through the intended process.

From where data/document is obtainable

leilaerfan@gmail.com ahankhah_saina@yahoo.com : Researchers who want to access the data can contact these emails or the mobile number : 09146307969.

What processes are involved for a request to access data/document

The applicant can access the data after the end of the study (about six months after the treatment) by sending an email to the scientific director of the study or by phone and explaining the reason for obtaining the data.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Leila Erfanparast

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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