

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Clinical retention comparison of fissure sealant versus flowable composite in type I adhesive conservative restorations after preparation with self etch bonding in children age 6-12

#### Protocol summary

##### Study aim

clinical retention comparison of fissure sealant versus flowable composite in type I adhesive conservative restorations after preparation with self etch bonding

##### Design

Clinical trial on 55 patients, 110 lower first molar teeth with parallel groups without blinding and randomization with coin toss

##### Settings and conduct

Selection of samples from the pediatric and community-oriented clients of Tabriz Dental School, obtaining informed consent from the patient's parents, determining caries by examination, tooth isolation and preparation of both sides and removing caries , using self-etch bonding on both sides and cure 10 s , apply the composite flow on one side and fissure sealant on the other side cure for 20-seconds at the end the occlusion will be checked ,comparison of retention after 3 and 6 months.

##### Participants/Inclusion and exclusion criteria

Entry conditions 1.Age group 6-12 years 2.Existence of first mandibular molar with caries limited to enamel on occlusal surface in both sides 3.Evidence of good oral hygiene at home 4.Patient cooperation and acceptance of treatment 5.No treatment has been done on the desired teeth before 6. The molar tooth is fully grown and can be isolated 7. No proximal caries Exit conditions 1.History of a medical condition that may interfere with treatment 2.Mention the history of allergies to restorative materials

##### Intervention groups

The tooth is isolated and prepared on both sides. On both sides self-etching bonding material will be used and dried then curing will be done for 10 seconds. On one side the composite flow is applied and on the other side the sealant will be placed and curing will be done for 20 seconds .

##### Main outcome variables

1.determining retention of preventive restoration while using composite flow, 2.determining retention of preventive restoration while using fissure sealant, 3.retention comparison of composite flow and fissure sealant

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210609051529N1**

Registration date: **2021-07-27, 1400/05/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-27, 1400/05/05**

Update count: **0**

##### Registration date

2021-07-27, 1400/05/05

##### Registrant information

##### Name

Naiemeh Shahveghar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3476 3163

##### Email address

shahvegharnaiemeh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-23, 1400/05/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical retention comparison of fissure sealant versus flowable composite in type I adhesive conservative restorations after preparation with self etch bonding in children age 6-12

**Public title**

Clinical retention comparison of fissure sealant versus flowable composite in type I adhesive conservative restorations

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age group 6-12 years Existence of first mandibular molar with caries limited to enamel on occlusal surface on both sides Evidence of good oral hygiene at home (regular brushing, flossing, regular fluoride therapy) Patient cooperation and acceptance of treatment (according to Frankel classification in group 3 or 4) No treatment has been done on the desired teeth before The molar is fully grown and can be isolated No proximal caries (evaluation by bite wing and clinical radiography)

**Exclusion criteria:**

History of a medical condition that may interfere with treatment Consumption of drugs that affect saliva and its quality Mention the history of allergies to any of the restorative materials

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **55**

More than 1 sample in each individual

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

2 mandibular first molar

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Assigning the type of restorative material to the right and left quadrants will be done randomly by dropping a coin, according to which flow composite is placed on the molar on one side and sealant on the other side.

**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 Tabriz University of Medical Sciences

**Street address**

17plaque , Sardrudi avenue,Shahriar st , Valiasr blvd , Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5157673879

**Approval date**

2021-05-22, 1400/03/01

**Ethics committee reference number**

IR.TBZMED.REC.1400.170

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

permanent tooth caries

**ICD-10 code**

K02.51

**ICD-10 code description**

Dental caries on pit and fissure surface limited to enamel

**Primary outcomes****1****Description**

Clinical retention of conservative restoration due to modified simonsen's criteria

**Timepoint**

3 and 6 month after finishing treatment

**Method of measurement**

Modified Simonsen's criteria

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The first lower molar is isolated on one side and prepared with bur no 329 after removing

carries two layer of self etch bonding is applied and cured for 10 seconds with light cure (400mw/cm<sup>2</sup>). The flow composite material (MASTER DENT, flow composite, USA) is then applied to the cavity and pit and fissures then cured again for 20 seconds. Finally, the occlusion is checked with articulator paper.

**Category**

Prevention

**2****Description**

Control group: The first lower molar is isolated on one side and prepared with bur no 329 after removing caries two layer of self etch bonding is applied and cured for 10 seconds with light cure (400mw/cm<sup>2</sup>). The fissure sealant (MASTERDENT, light cure pit and fissure sealant, U.S.A) is then applied to the cavity and pit and fissures then cured again for 20 seconds. Finally, the occlusion is checked with articulator paper.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Pediatric and community-based section of Tabriz dental university

**Full name of responsible person**

Leila Erfanparast

**Street address**

Tabriz dental school , Tabriz medicine university , Goltasht st, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5965

**Fax**

+98 41 3334 6977

**Email**

dent.fac@tbzmed.ac.ir

**Web page address**

<https://dentistryfac.tbzmed.ac.ir>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Samii

**Street address**

Tabriz faculty of dentistry , Goltasht st ,Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 5965

**Fax**

+98 41 3334 6977

**Email**

dent.fac@tbzmed.ac.ir

**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**

70

**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

**Street address**

Pediatric ward, Tabriz faculty of dentistry, Goltasht st., Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

041 3335 5965

**Phone**

+98 41 3335 5965

**Email**

erfanparast.l@tbzmed.ac.ir

**Person responsible for scientific 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

**Street address**  
Pediatric ward, Tabriz faculty of dentistry, Golgasht  
st., Tabriz

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Tabriz

**Province**  
East Azarbaijan

**Postal code**  
5166614711

**Phone**  
+98 41 3335 5965

**Email**  
erfanparast.l@tbzmed.ac.ir

## 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

**Street address**  
Pediatric wand, Tabriz faculty of dentistry, Golgasht  
st., Tabriz

**City**  
Tabriz

**Province**  
East Azarbaijan

**Postal code**

5166614711

**Phone**  
0098904133355965

**Email**  
erfanparast.l@tbzmed.ac.ir

## 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 is potentially shareable after unidentifying  
individuals

### When the data will become available and for how long

6 months from the start of research and preparation of  
new results

### To whom data/document is available

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

### Under which criteria data/document could be used

It can be used to perform similar research with intended  
process

### From where data/document is obtainable

To receive data, send an email to Dr. Erfanparast  
(Pediatric dentist of Tabriz Dental School) :  
erfanparast.l@tbzmed.ac.ir

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

An applicant can access the study after the end of the  
study (about 6 months after the treatment) by sending  
an email to the study supervisor or by phone and  
explaining the reason for obtaining the data.

### Comments