Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

caries two layer of self etch bonding is applied and cured for 10 seconds with light cure (400mw/cm2). 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/cm2). The fissure sealent (MASTERDENT,light cure pit and fissure sealent,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 , Golgasht 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 , Golgasht 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, Golgasht 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
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 5965
Email
erfanparast.l@tabzmed.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 unidentifieing 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