Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite

Protocol summary

Study aim
Comparison of clinical performance of resin based pit and fissure sealant with self-adhesive flowable composite resin.

Design
A clinical trial with two simultaneous interventions on the same individuals, with parallel groups, with a sample size of 40 patients and two samples from each patient, double blinded without randomization method.

Settings and conduct
This project will be carried out in the pediatric department of Kerman Dental School by one pediatric dental resident. Prior to treatment, parents will be given explanations about the clinical procedure and treatment rationale. Follow-up evaluations are performed by the same researcher and, if necessary, by two other researchers, who will comment on clinical criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: children aged 6 to 12 years old; absence of cl I, cl II and cl v caries lesions in permanent mandibular first molars; possibility of isolation with cotton roll; presence of fully erupted teeth; absence of oral habits such as clenching; bruxism and heavy occlusion in the studied teeth; absence of previous dental treatment on the mandibular permanent first molars; molars with deep pit and fissures susceptible to caries lesion in the future; no medical systemic problems interfering in the study and not taking any medication which affects the saliva flow. Exclusion criteria: inability to be properly isolated by the operator; uncooperative children; permanent mandibular first molars with dentin caries lesion; the presence of opaque-gray shadows on the bottom of the grooves and the presence of grooves and fissures with brownish-gray color branching from the center of the groove to the around of the groove or pit.

Intervention groups
Intervention No. 1: Flowable self-adhesive composite
Intervention No. 2: Resin based pit and fissure sealant

Main outcome variables
self-adhesive composite retention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180521039763N4**
Registration date: **2021-04-15, 1400/01/26**
Registration timing: **prospective**

Last update: **2021-04-15, 1400/01/26**
Update count: **0**

Registration date
2021-04-15, 1400/01/26

Registrant information

Name
Fatemeh Jahanimoghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3211 8071

Email address
jahanimoghadam@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite

Public title
Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 6 to 12 years Permanent first molars of the mandible with no cl I, cl II and cl v caries lesion Possibility of isolation with cotton roll Fully erupted permanent molars Absence of oral habits such as clenching, bruxism and heavy occlusion in the studied teeth Absence of previous dental treatment on the first permanent mandibular molars Molars with deep pit and fissures with the susceptibility of future caries Absence of interfering medical systemic problems in the study Not consuming any drugs that affect saliva flow
Exclusion criteria:
Unablity of the operator for proper isolation Uncooperative child Permanent first mandibular molars with dentin caries lesions Existence of opaque-gray shadows on the bottom of the grooves Existence of grooves and fissures with brown-gray discoloration branching from the center of the groove to around of the groove or pit
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **2**
For each patient, two permanent first mandibular molars will be considered. The 80 studied teeth will be divided into two groups of 40. All teeth were treated by the same operator. First, the surface of the teeth is cleaned of debris and plaque with a rotating brush, and after washing and drying the tooth surfaces and examining the occlusion with articulating paper, each tooth is isolated by a cotton roll inside the buccal and lingual vestibule. Then, the tooth surfaces of both groups are prepared for placement of two types of materials for pit and fissure sealant, so that in each patient, the first permanent lower molar tooth on the bottom right is sealed with self-adhesive flowable composite resin with (Vertise Flow with A2 color from Kerr company, USA) and the first permanent lower molar tooth on the left side is sealed with the light cure pit and fissure-sealant resin with A2 color (Master-Dent company from USA)

Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in this clinical trial are not aware of the type of material used to treat each of their teeth, and the statistics consultant is not aware of the type of treatment performed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman university of medical sciences
Street address
Kerman University of Medical Sciences, Shafa crossroad, Jomhuri Eslami Blvd.
City
Kerman
Province
Kerman
Postal code
7618759689
Approval date
2021-01-21, 1399/11/02
Ethics committee reference number
IR.KMU.REC.1399.556

Health conditions studied

1

Description of health condition studied
Dental caries
ICD-10 code
K02
ICD-10 code description
Dental caries

Primary outcomes

1

Description
Self-adhesive composite retention and incidence of secondry caries
Timepoint
3, 6, 12 months

Method of measurement
Clinical examination with a dental probe and a dental mirror

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, the surface of the first permanent lower right molar in each patient is cleaned of debris and plaque by a rotating brush, and after rinsing and drying the dental surfaces and examining the occlusion by articulating paper, it is isolated by a cotton roll inside the buccal lingual vestibule. Then, according to the manufacturer instructions of the self-adhesive flowable composite (Vertise flow) based on the no need for acid etching and bonding process before placing the composite, after drying the teeth, the self-adhesive composite (with maximum thickness of 0.5 mm) by using a microbrush is placed on the grooves of the teeth for 20 seconds and then cured for 40 seconds using a light curing device (Coltene AG, Altstatten, Coltolux Switzerland).
Category
Prevention

2

Description
Intervention group: First, the surface of the first permanent lower left molar in each patient was cleaned of debris and plaque with a rotating brush, and after washing and drying the tooth surfaces and examining the occlusion by articulator paper, it was isolated by a cotton roll inside the buccal and lingual vestibule. Then pits and fissures of the occlusal surfaces of the molar are etched with 37% phosphoric acid (Brasil / FGM) for 20 seconds and then rinsed with water for 15 seconds and dried by gentle air flow. If the etching surfaces are contaminated with saliva, the tooth surface will be etched again for 10 seconds. Then, two layers of Adper bonding are applied and a gentle stream of air is used for five seconds to evaporate the solvent, and then the curing is performed with a light curing device for 20 seconds, after that the resin-based pit and fissure sealant is placed on the bonding. After ensuring the absence of voids by gently moving the dental probe over the pit and fissures, the sealant is cured for 40 seconds.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman university of medical sciences, faculty of dentistry
Full name of responsible person
Reyhane Aftabi
Street address
Shafa avenue
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
reyhane9495@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Deputy of research and technology, Kerman University of Medical Sciences, Ibn Sina Ave., Somayeh crossroad (Tahmasb Abad),
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3855
Email
abpardakhty@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Reyhane Aftabi
Position
Pediatric dentistry resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, adjacent to Shafa Hospital, Shafa Ave.
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
00883432119021
Email
reyhane9495@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reyhane Aftabi
Position
Pediatric dentistry resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, adjacent to Shafa Hospital, Shafa Ave.
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
reyhane9495@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Reyhane Aftabi
Position
Pediatric dentistry resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, adjacent to Shafa Hospital, Shafa Ave.
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
reyhane9495@gmail.com

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
Only a portion of the data is shared, such as the original outcome information
When the data will become available and for how long
Start the access period, 6 months after printing the results
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
For researchers
From where data/document is obtainable
reyhane9495@gmail.com
What processes are involved for a request to access data/document
1 month
Comments