

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of clinical success of the application of a universal adhesive in etch-and-rinse and etch-and-dry in fissure sealant of first permanent molar

Protocol summary

Summary

(1) Objectives Comparison of the clinical success of the use of a universal adhesive system in two method: etch-and-rinse and etch-and-dry and (2) Design Double blind split mouth randomized controlled clinical trial study (3) Setting and conduct After obtaining written consent from the parents of the selected children, the fissure sealant of the first permanent molars of the participants is done by applying a universal adhesive system in two different method. (4) Participants including major eligibility criteria 6 to 12 years old children with intact first permanent molars (5) Intervention Two method of applying adhesive: 1- etch-and-rinse technique, 2-etch-and-dry technique (6) main outcome measures (primary and secondary outcome variables) In the 6-month and one-year follow up, fissure sealants are evaluated in terms of discoloration, caries, and retention by a blind examiner.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100930228N1**

Registration date: **2017-09-19, 1396/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

marzie boskabady

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 2564

Email address

boskabadymr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical success of the application of a universal adhesive in etch-and-rinse and etch-and-dry in fissure sealant of first permanent molar

Public title

The effect of etching and not etching in clinical success of fissure sealants with a universal adhesive

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having two healthy first permanent molar; healthy 6 to 12 years old children Exclusion criteria: known allergy to the used resin materials; detectable dental caries in selected teeth; previous sealant or restoration; bruxism or malocclusion; Reluctance of patient to return for follow up and re-

evaluation
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
mashhad university of medical sciences
Street address
mashhad-vakilabad blv- opposite of mellat park-
dental school
City
mashhad
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.mums.sd.REC.1394.164

Health conditions studied

1
Description of health condition studied
prevention of dental caries in pit and fissures of
permanent first molar
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
retention

Timepoint
6 month and 1 year after sealant therapy
Method of measurement
full retention, partial loss, total loss

Secondary outcomes

1
Description
dental caries using ICDAS2 visual classification
Timepoint
6 month and 1 year after sealant therapy
Method of measurement
score 0: intact surface near sealant margins, score 2:
first evidences of demineralization after drying the
surface, score 3: obvious visual color changes

Intervention groups

1
Description
intervention group 1: etch-and-rinse technique and then
apply universal adhesive
Category
Prevention

2
Description
control group: apply universal adhesive without primary
etch
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
mashhad dental school- pediatric dentistry
department
Full name of responsible person
dr marzie boskabady
Street address
City
mashhad

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
mashhad university of medical sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
daneshgah street- ghoreishi building

City
mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
mashhad 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
mashhad university of medical sciences

Full name of responsible person
marzie boskabady

Position
assistant professor

Other areas of specialty/work

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vakil abad boulevard-opposite of mellat park

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Assistant Professor of Pediatric Dentistry, Dental Materials Research Center, School of Dentistry, M

Full name of responsible person
marzie boskabady

Position
pediatric dentistry

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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