

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Clinical and radiographic evaluation of the progression of the proximal enamel caries in the molars after resin infiltrations compared with tooth mousse.

Protocol summary

Study aim

Clinical and radiographic results of progression of proximal enamel caries in children's molars after infiltration resin compared to tooth mousse

Design

Randomized clinical trial

Settings and conduct

The study is carried out at the Faculty of Dentistry, University of Tehran.

Participants/Inclusion and exclusion criteria

Children with at least two molar caries can be included in the study and children with systemic diseases or noncommunicable do not qualify for inclusion.

Intervention groups

One is the molar group where the resin is applied and the other is the paste.

Main outcome variables

This study can be used to prevent the progression of proximal caries if it is found that infiltration resin and tooth mousse paste treatments have significant effects on preventing the progression of proximal caries lesions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045114N1**

Registration date: **2020-03-15, 1398/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

mona mansourvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 3340

Email address

ghazalebaniebrahimi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and radiographic evaluation of the progression of the proximal enamel caries in the molars after resin infiltrations compared with tooth mousse.

Public title

Clinical and radiographic evaluation of the progression of the proximal enamel caries in the molars after resin infiltrations compared with tooth mousse.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Children with at least two of the molars with enamel caries.

Exclusion criteria:
Caries that have become cavities.

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: **25**
More than 1 sample in each individual
Number of samples in each individual: **2**
Children with at least two of the molars with enamel caries.

Randomization (investigator's opinion)
N/A

Randomization description

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

Iran national committee for ethics in biomedical research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.

City

tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-08-07, 1398/05/16

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.100

Health conditions studied

1

Description of health condition studied

Clinical and radiographic evaluation of the progression of

the proximal enamel caries in the molars after resin infiltrations compared with tooth mousse

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

enamel caries

Timepoint

At baseline and one, three, six months thereafter

Method of measurement

Clinical and radiographic measurements

Secondary outcomes

1

Description

Stop enamel caries

Timepoint

At baseline and one, three, six months thereafter

Method of measurement

Clinical and radiographic measurements

Intervention groups

1

Description

Intervention group 1: Moles on which resin is applied. Resin is a treatment infiltration that is performed by the dentist to prevent the caries from progressing. The treatment is performed once and the approximate duration of application of the resin is 5 minutes.

Category

Prevention

2

Description

Intervention group: Moles on which the paste is applied. tooth mousse should be used once daily to prevent the caries from progressing.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, University of Tehran

Full name of responsible person

Ghazale Baniebrahimi

Street address

Mahan street, Khani abad no, Tehran, Iran

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1988644458
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran 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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ghazale Baniebrahimi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work

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Person responsible for updating data

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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

Part of the data, such as information about the main outcome or the like

When the data will become available and for how long

Access started several months after the study was completed and the results reviewed

To whom data/document is available

Everyone can take action

Under which criteria data/document could be used

No conditions

From where data/document is obtainable

Department of Pediatrics, Faculty of Dentistry, University of Tehran

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

No conditions

Comments