

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness of Fluoride Varnish in Remineralization of Incipient Carious Lesion during a 7-month period by means of paraclinical criteria (Diagnodent)

Protocol summary

Summary

Objective: this study is designed to assess the effectiveness of fluoride varnish application every three months on incipient enamel lesions in compare to those who have not received this intervention. Methods: 208 tooth surfaces in 6-12 years of age children are divided randomly to case and control. The cases will receive fluoride varnish application at three month intervals. For the control group precise and individual oral hygiene instruction will be provided every three months and tooth brushes and dentifrices are also given to them at these visits. Evaluation of enamel lesion will be accomplished by Diagnodent after 7 months to evaluate the effects of this intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110221861N3**

Registration date: **2012-01-27, 1390/11/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-27, 1390/11/07

Registrant information

Name

Katayoun Salem

Name of organization / entity

Tehran Azad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dental Research center of Guilan Dental School

Expected recruitment start date

2011-11-01, 1390/08/10

Expected recruitment end date

2012-06-01, 1391/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Fluoride Varnish in Remineralization of Incipient Carious Lesion during a 7-month period by means of paraclinical criteria (Diagnodent)

Public title

Fluoride Varnish versus Oral Hygiene Instructions in Control of Incipient carious Lesions

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Discoloration or white opacities with explorer wedge in the fissures of first permanent molar.
Exclusion Criteria: Any Hypoplastic defects on enamel surface.

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: 208

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research, Guilan University of Medical Sciences

Street address

Namjoo Blvd

City

Rasht

Postal code

Approval date

2011-08-27, 1390/06/05

Ethics committee reference number

3900906603

Health conditions studied

1

Description of health condition studied

Incipient Enamel caries

ICD-10 code

K02.0

ICD-10 code description

Caries limited to enamel

Primary outcomes

1

Description

Dental caries

Timepoint

Every three monthys

Method of measurement

clinical examination (color, consistency, diameter) and Diagnodent (score)

Secondary outcomes

1

Description

Oral Hygiene

Timepoint

At the beginning and after completing the study

Method of measurement

Simplified Oral Hygiene Index

Intervention groups

1

Description

Interventional Group:At first the surface of first permanent molars are cleansed by the means of prophylaxis paste and rubber cup.Then the tooth surface is dried by a blast of air and isolated with cotton rolls. Fluoride varnish is applied as a thin layer all around the tooth surface and keep isolated for 15 seconds.The patients are instructed not to chew for 2 hours and avoid tooth brushing until the next day.

Category

Prevention

2

Description

Control group: Subjects in this group will receive face to face oral hygiene instructions individually including tooth brushing by scrub method ,flossing and dietary consultation.Prophylaxis will be repeated every three months and they also will receive free toothbrush and toothpaste every three months. Final evaluation will take place at the end of 7 months.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan Dental School and primary schools of the Rasht

Full name of responsible person

Dr Katayoun Salem

Street address

Opposite Pardis Hotel, Imam Blvd.

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chnceller of Research and Technology, Guilan
University of medical sciences

Full name of responsible person

Dr Rasool Tabari

Street address

Azodi Blvd.

City

Rasht

Grant name

بودجه مصوب معاونت فناوری

Grant code / Reference number

621/987پ

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

Yes

Title of funding source

Vice Chnceller of Research and Technology, Guilan
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

Guilan Dental school

Full name of responsible person

Dr Javaneh Vejdani

Position

Assistant Professor, Guilan Dental school

Other areas of specialty/work

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Person responsible for scientific inquiries

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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