

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect of fluoride varnish with silver diamine fluoride on oral pH in the period of primary teeth

Protocol summary

Study aim

Comparing the effect of fluoride varnish with silver diamine fluoride on oral pH in pediatric deciduous teeth

Design

Clinical trial with two groups in parallel, not blind, randomized, Excel software rand function was used for randomization

Settings and conduct

In this study, which is performed in the pediatric ward of Tehran Dental School, all samples should be brushed without prophylaxis paste before any work so that plaque is removed and dental surfaces are free of debris. Immediately after brushing, PH The mouth is marked with pH meter paper and its number is recorded. Working conditions are the same for all samples and all tests are performed by one person, and for all samples, cotton roll and suction are used to establish isolation and standardize the conditions.

Participants/Inclusion and exclusion criteria

Admission requirements: The child should be between 5 and 7 years old, The child should not have any systemic disease, should not have any mental disability, patient cooperation should be good, understand Persian language, should not have herpes And herpes and no dry mouth. Exclusion criteria: The child has a systemic disease or dry mouth, mental disability, herpes and herpes, does not understand Persian and his cooperation is low.

Intervention groups

In this study, in order to evaluate the effectiveness of silver diamine fluoride (SDF) on the pH of the mouth of children with deciduous dental system and compare it with fluoride varnish, the samples were divided into two groups and to the first group after isolation, fluoride varnish was applied on The teeth and the pH of the mouth was assessed at various times. For the second group, SDF was applied after isolation and oral pH was measured at 5 times.

Main outcome variables

The rate of change in oral pH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200727048218N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **retrospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Sara Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2625 5095

Email address

minaakbari316@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-24, 1398/10/03

Expected recruitment end date

2020-01-25, 1398/11/05

Actual recruitment start date

2019-12-24, 1398/10/03

Actual recruitment end date

2020-01-23, 1398/11/03

Trial completion date

2020-01-23, 1398/11/03

Scientific title

Comparison of the effect of fluoride varnish with silver diamine fluoride on oral pH in the period of primary teeth

Public title

Comparison of the effect of fluoride varnish with silver diamine fluoride on children's teeth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Understand Persian language The patient should be between 5 and 7 years old

Exclusion criteria:

The child have any systemic disease The child has any mental disability Patient cooperation is not good Do not understand Persian language Have herpes The child have xerostomia The child's dental system is mixed dentition

Age

From **5 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Actual sample size reached: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into two equal groups using randomization with six random blocks with the help of Excel software. In each block, three samples are placed in group A and three samples in group B and the randomization process is studied by the methodology consultant. Done and researchers are conceal of it.

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 Tehran University of Medical Sciences

Street address

Dibaji jonubi St,Rahmani St,Negin dibaji complex,No5

City

Tehran

Province

Tehran

Postal code

1918799913

Approval date

2019-12-10, 1398/09/19

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.159

Health conditions studied

1

Description of health condition studied

PH of children's mouths

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Silver diamine fluoride

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The pH of children's mouths

Timepoint

Immediately after treatment, then 5 minutes later, after 10 minutes, after 20 minutes and after 30 minutes using pH paper, oral pH is measured and recorded

Method of measurement

By pH paper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The samples are randomly divided into two groups and the first group is given 5% fluoride varnish (V-varnish / Korea / fluoride varnish / 0.4 ml) with V-varnish brand. Immediately after fluoride varnishing, then 5 minutes later, after 10 minutes, after 20 minutes and after 30 minutes using oral pH meter paper, the pH of the mouth is measured and recorded.

Category

Prevention

2

Description

Intervention group: For the second group, silver diamine fluoride 30% (SDF) (cariestop30% / Iran / biodinamica / ml5) is used. Immediately after SDF application, 5 minutes later, after 10 minutes, after 20 minutes, and after 30 minutes, the pH of the mouth is measured and recorded using pH meter paper.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran university of dentistry

Full name of responsible person

Sara Akbari Masouleh

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Dibahi jonubi St,Rahmani St,Negin dibaji complex,No5

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marzieh Alikhasi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran university of medical science

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

Donya alinejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available