

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of salivary fluoride level following school_based fluoride varnish program and professional fluoride varnish therapy in dental office among 6-12 years old children

Protocol summary

Study aim

Comparison of salivary fluoride level following school_based fluoride varnish program and professional fluoride varnish therapy in dental office among 6-12 years old children

Design

Clinical trial, Randomized, Single blinded, Sample size : 24(pilot), Number of people in each group : 12

Settings and conduct

Saliva will be collected by dental student before and 30 minute after fluoride varnish application in schools and in dental clinic(by pediatric dentistry specialist) and salivary fluoride concentration will be analyzed with ion selective electrode of fluoride Data will be analyzed using analysis of covariance ANCOVA at a $p < 0.05$ level of significance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. 6-12 years old children 2. People with good oral hygiene (who brush their teeth twice daily) Exclusion criteria: 1. People with salivary flow rate lesser than 0.25 _1 ml/min 2. People with kidney disorders 3. Lack of cooperation for fluoride therapy or saliva collection 4. People who are resident in the area with lesser than 0.2 ppm fluoride in drinking water.

Intervention groups

1. Salivary sample will be collected before and 30 minutes after fluoride therapy which is done in schools.
2. Salivary sample will be collected before and 30 minutes after fluoride therapy which is done by pediatric dentist in dental office.

Main outcome variables

Salivary fluoride level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200411047018N2**

Registration date: **2020-11-19, 1399/08/29**

Registration timing: **prospective**

Last update: **2020-11-19, 1399/08/29**

Update count: **0**

Registration date

2020-11-19, 1399/08/29

Registrant information

Name

Azin Sohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3332 2938

Email address

azin.sohrabi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of salivary fluoride level following

school_based fluoride varnish program and professional fluoride varnish therapy in dental office among 6-12 years old children

Public title

Comparison of salivary fluoride level following school_based fluoride varnish program and professional fluoride varnish therapy in dental office among 6- 12 years old children

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

6-12 years old children People who have good oral hygiene and brush their teeth twice daily with fluoride containing dentifrices

Exclusion criteria:

People with salivary flow rate lesser than 0.25 _1 ml/min Children with kidney disorders Lack of cooperation for fluoride therapy or collection of saliva People who are resident in the area with lesser than 0.2 ppm fluoride in drinking water

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced (permuted) Block Randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer does not know the type of consumable and consumable is marked with codes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tabriz university of medical sciences

Street address

Tabriz university of medical sciences, Golghasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

-

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.TBZMED.RES 1399.701

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

Salivary fluoride concentration

Timepoint

Before the intervention and 30 minutes after intervention

Method of measurement

Ion selective electrode of fluoride

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The subject will get school based fluoride varnish therapy

Category

Prevention

2

Description

Intervention group: The subject will get professional fluoride therapy by pediatric dentistry specialist in dental clinic

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of tabriz university of medical sciences

Full name of responsible person

Azin Sohrabi

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Pediatric dentistry department, Dental faculty,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mozhgan Kachoei

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Kachoei@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Azin Sohrabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available