

# 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 then 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

**Street address**

Pediatric dentistry department, Dental faculty,  
Golgasht ave.

**City**

Tabriz

**Province**

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**Postal code**

-

**Phone**

+98 41 3355 5969

**Email**

azin.sohrabi@gmail.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mozhgan Kachoei

**Street address**

Dental faculty, Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

-

**Phone**

+98 41 3334 0310

**Email**

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

**Street address**

Dental faculty, Golgasht Ave.

**City**

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**Province**

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0098 3335 9659

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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### Person responsible for updating data

**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**

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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