

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison the effectiveness of Fluoride Varnish and Oral Health Education on Prevention of Dental Caries in Primary teeth in Children under the Age of Three Years

#### Protocol summary

##### Summary

The aim of this study was to evaluate the clinical efficacy of oral health education and a fluoride varnish in the prevention of caries in children. In this clinical study 300 children under the age of 3 with at least 4 erupted tooth, among local public health care centers in Shiraz were selected. The children randomly divided into three groups. 1) control; no preventive intervention; 2) oral health counseling; and 3) oral health counseling and fluoride varnish at baseline and six months later. Each group contained 100 children. This research was randomized, single blind with placebo control and the aim was prevention and reduction of dental caries in primary teeth. A file according to the patient's demographic characteristics and the number of erupted teeth was formed for each child. Two dentistry interns cooperated on practical steps of the project and in evaluation periods in 4, 8 and 12 months after the base line. The caries index (dmft) was used to examine the teeth as primary outcome. Also the parents knowledge and performance regarding oral health in children in each group was assessed by using a questionnaire as secondary outcome. The outcome was the influences of each method in caries reduction in children.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508127402N5**

Registration date: **2015-08-26, 1394/06/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-26, 1394/06/04

#### Registrant information

##### Name

Mahtab Memarpour

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1626 3192

##### Email address

memarpour@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shiraz University of Medical Sciences

#### Expected recruitment start date

2013-03-20, 1391/12/30

#### Expected recruitment end date

2014-03-20, 1392/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison the effectiveness of Fluoride Varnish and Oral Health Education on Prevention of Dental Caries in Primary teeth in Children under the Age of Three Years

#### Public title

Comparison of Fluoride Varnish and Oral Health Education on Prevention of Dental Caries in Primary teeth

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: children who were between 12 and 24 months of age at the beginning of the study; all participants had at least four erupted primary teeth and none of the teeth showed signs of non-cavitated or cavitated caries (dmft=0); the parents did not use any prevention of dental caries at home or in other clinics. Exclusion criteria: medical histories of systemic diseases in children; drug allergies; congenital physical disabilities; mental disabilities; dental anomalies.

#### Age

From **1 year** old to **3 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **300**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Postal code

00987112122389

#### Approval date

2013-09-23, 1392/07/01

#### Ethics committee reference number

Ct-p-92-6158

## Health conditions studied

### 1

#### Description of health condition studied

dental caries

#### ICD-10 code

K02.0

#### ICD-10 code description

Caries limited to enamel

## Primary outcomes

### 1

#### Description

dental caries reduction

#### Timepoint

4, 8 and 12 months after base line

#### Method of measurement

dmft index assess by dental examination with using dental mirrors and ball-ended probes

## Secondary outcomes

### 1

#### Description

parents' knowledge toward oral health

#### Timepoint

4, 8 and 12 months after base line

#### Method of measurement

self reporting questionnaire

### 2

#### Description

parents' performance toward oral health

#### Timepoint

4, 8 and 12 months after base line

#### Method of measurement

self reporting questionnaire

## Intervention groups

### 1

#### Description

group 1(control): The control group participants did not receive any oral health care intervention or treatment for caries prevention. The placebo was used similar to material used in group 3.

#### Category

Placebo

### 2

#### Description

group 2. Oral health counseling in each follow up times. The placebo was used similar to material used in group 3.

#### Category

Prevention

### 3

#### Description

group 3; fluoride varnish application in the base line and 6 months later. Oral hygiene counseling in each follow up times.

**Category**  
Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Public Health Care Centers in Shiraz (Valfajr,...)  
**Full name of responsible person**  
Mahtab Memarpour  
**Street address**  
Department of Pediatric Dentistry, School of  
Dentistry, Ghomabad  
**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr Postfroosh Fard  
**Street address**  
Shiraz University of Medical Sciences, Zand Street  
**City**  
Shiraz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Mahtab Memarpour  
**Position**  
Professor, Department of Pediatric Dentistry  
**Other areas of specialty/work**  
**Street address**  
Department of Pediatric Dentistry, School of

Dentistry, Ghomabad, Ghasrodasht

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**Phone**  
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memarpour@sums.a.cir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Professor, Department of Pediatric Dentistry  
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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*