

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of Pascal and Preventa fluoride varnishes on Streptococcus mutans count in saliva in children 4-6 years old(in vivo study)

#### Protocol summary

##### Summary

(1) Tooth decay is one of the most common human infectious diseases, specially in children. (2) This research has been done to prove the importance of varnish fluoride; This study is based on the influence of two kinds of varnish fluoride: Pascal and Preventa in amount of salivary streptococcus mutans bacteria. (3,4) The data are collected by choosing 38 kids of a kindergarten (ranging 4\_6) and dividing them into two groups of 19 randomly. Their milk teeth must be free of decay or have initial caries. (5) Initial samples of unstimulated saliva are collected one hour after eating and brushing. Then one group are applied Pascal varnish fluoride and the other one are applied Preventa type. After 24 hours saliva samples of two groups are collected again. (6) The samples will be sent to microbiology laboratory in order to identify and account of bacteria.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102630521N1**

Registration date: **2017-06-17, 1396/03/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-17, 1396/03/27

##### Registrant information

###### Name

maryam kazemi

###### Name of organization / entity

jondi shapour university medical of science

###### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4326 1182

##### Email address

kazemi.ma@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz university of medical science, Vice chancellor for research

##### Expected recruitment start date

2017-04-26, 1396/02/06

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Pascal and Preventa fluoride varnishes on Streptococcus mutans count in saliva in children 4-6 years old(in vivo study)

##### Public title

The effect of Pascal and Preventa fluoride varnishes on Streptococcus mutans count in saliva

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. in clinical examination at the time of the study have caries free primary dentition or initial caries; 2. No history of antibiotics for the past one month; 3.No history of fluoride treatment for the past six month; 4. The children do not have any contraindications to apply fluoride therapy; 5. children 4 to 6 years old.

##### Age

From **4 years** old to **6 years** old

##### Gender

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 38

**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**

Ahvaz Jondi shapoor university of medical science,  
Ethics Committee

**Street address**

ground floor, Department of Development Research  
and Technological University of Medical Sciences and  
Health Services Ahvaz, City University

**City**

ahvaz

**Postal code**

6135715794

**Approval date**

2016-12-24, 1395/10/04

**Ethics committee reference number**

IR.AJUMS.REC.1395.578

**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**

streptococcus mutans count

**Timepoint**

24 hours after application of fluoride varnish

**Method of measurement**

Colony forming unit

**Secondary outcomes**1**Description**

do not have

**Timepoint**

do not have

**Method of measurement**

do not have

**Intervention groups**1**Description**

The application of fluoride varnish, Pascal fluoride  
varnish, 5% Sodium Fluoride, single dose, frequency of  
use once, A small brush or applicator is then used to  
apply the varnish, Inc. Pascal America

**Category**

Prevention

2**Description**

The application of fluoride varnish, Preventa fluoride  
varnish, 5% Sodium Fluoride, single dose, frequency of  
once-a, A small brush or applicator is then used to apply  
the varnish, the Asian pharmaceutical chemistry  
medicine in Iran

**Category**

Prevention

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Department of Pediatrics, School of Dentistry

**Full name of responsible person****Street address****City**

ahvaz

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technological  
Development Jundishapur University of Medical  
Science

**Full name of responsible person**

Mohsen safi

**Street address**

ground floor, Research and technology development  
department of Ahvaz University of Medical Sciences,  
university town

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research and Technological  
Development Jundishapur University of Medical Science

**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**

Department of Pediatrics, Faculty of Dentistry, Ahvaz  
University of Medical Sciences

**Full name of responsible person**

Dr Leila Basir

**Position**

Professor of Pediatric Dentistry, Professor and Head of  
Department

**Other areas of specialty/work**

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University

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## Person responsible for scientific inquiries

**Contact**

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Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Razie Meshki

**Position**

Professor of Pediatric Dentistry

**Other areas of specialty/work**

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Golestan highway, Ahvaz

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Maryam Kazemi

**Position**

Dental student

**Other areas of specialty/work**

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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*