

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)

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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
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Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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Professor of Pediatric Dentistry

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Person responsible for updating data

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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