Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 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

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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 Department

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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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Dental student

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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