Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effectiveness of Fluoride Varnish and Casein Phosphopeptide Amorphous Calcium Phosphate (CCP-ACP) on remineralization of white spot lesions of primary teeth enamel:An in vivo study

Protocol summary

Summary

The present study aimed to assess the clinical impact of the combination of Fluoride Varnish and Casein Phosphopeptide Amorphous Calcium Phosphate in reminalization of white spot lesions on the enamel of deciduous teeth in children. In this clinical study, 160 children under 3 years of age with the eruption of at least four anterior maxillary teeth are elected from the Health Centers in deprived areas of the city. None of the patients' teeth have a caries with cavity. Then 160 children are placed randomly in one of the following groups. Each group is included of 40 children having at least two teeth with white spot lesions. This research is randomized, single blind with no placebo control and the aim is prevention and reduction of dental caries in primary teeth. Objectives and methods of the research is explained to parents and if they desire to participate in the research project, a written consent form is received from them. A file according to the patient's demographic characteristics and the number of erupted teeth is formed for each child. Areas of white spot lesions in a dental chart is drawn. Two dentistry interns cooperate on practical steps of the project and in evaluation periods, examine the children without the knowledge of experimental groups (blind). Then decalcification index is used to examine changes in lesions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207077402N2**
Registration date: **2012-08-25, 1391/06/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-08-25, 1391/06/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-06-24, 1391/04/04

Expected recruitment end date

2013-06-24, 1392/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of Fluoride Varnish and Casein Phosphopeptide Amorphous Calcium Phosphate (CCP-ACP) on remineralization of white spot lesions of primary teeth enamel:An in vivo study

Public title
Using of Fluoride Varnish in caries reduction
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: children under 3 years of age; with the eruption of at least four anterior maxillary teeth; having white spot lesions. Exclusion criteria: Children having caries with cavity
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: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not 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
www.sums.ac.ir
City
Shiraz
Postal code
Approval date
2012-07-03, 1391/04/13
Ethics committee reference number
CT-91-6101

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
Changes in enamel decalcification
Timepoint
every 3 months for one year
Method of measurement
Also dimensional changes in sizes and number of white spot will evaluate according to enamel decalcification and register in patients' follow-up form.

Secondary outcomes

1

Description
no changes in enamel decalcification
Timepoint
every 3 months for one year
Method of measurement
Also dimensional changes in sizes and number of white spot will evaluate according to enamel decalcification and register in patients' follow-up form.

Intervention groups

1

Description
Fourth group: dental hygiene instruction and proper nutrition counseling along with the daily use of tooth mouse (GC, Japan). A package containing a finger toothbrush, a tube of tooth mouse and an educational pamphlet is given to the parents. The same training methods used in Group 2 is repeated.Then the method of using the mouse is taught to parents; in the way that a parent after brushing teeth, places tooth mouse by a swab twice a day (morning and night before bed) and 10 minutes (at least 3 minutes) on the teeth. The patient should be avoided from eating and drinking for half an hour . It should be mentioned that the parents are ensured that the CCP-ACP composition is derived from milk and for baby has no risk. However, if desired, parents can wash the baby's mouth after half an hour. It should be noted that the instructions are repeated every three weeks in the first 3 months in order to increase the knowledge of parents and thereafter the examinations and oral hygiene instructions is repeated each month.
Category
Prevention

2

Description
First group: Controlled group without any remedy or hygiene and nutrition counseling In order to prevent dental caries.
Category

N/A

3

Description

Second group: Dental health education and advice on proper nutrition for decreasing the probability of dental caries. The cleaning of infant's teeth using a finger brush (Panbeh riz - Iran) that they are freely available, is shown face to face to the parent.Also the causes of baby bottle syndrome, its prevention methods and the pattern of proper nutrition in prevention of caries is fully explained and they are given an educational pamphlet. In this pamphlet the items such as the importance of the decidious teeth, caring and cleaning them, the impact of drinking milk at night in developing caries and ... is described (attached forms). Also three posters with the focus on the importance of the deciduous teeth and the preventive methods of dental caries is prepared and hanged in health centers. It should be noted that the instructions are repeated every three weeks in the first 3 months in order to increase the knowledge of parents and thereafter the examinations and oral hygiene instructions is repeated each month.

Category

Prevention

4

Description

Third group: dental hygiene instruction and proper nutrition counseling with the application of fluoride varnish: Initially after educating patient's parent, the teeth are cleaned with a toothbrush provided by the dentist. Then the tooth surfaces are dried using a sterile gauze and are isolated with placing the cotton rolls on vestibule. After that fluoride varnish containing sodium fluoride 5% (DuraShield, Sultan, USA) using a disposable brush is placed on all tooth surfaces and left isolated for 1 minute. Parents are advised not to use abrasive foods during the day and not to brush at night. The above procedure is repeated every 4 months. . It should be noted that the instructions are repeated every three weeks in the first 3 months in order to increase the knowledge of parents and thereafter the examinations and oral hygiene instructions is repeated each month.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Health Centers(ValFajr,...)

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Poust Foroushfard

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

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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