

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)

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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
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Position
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Person responsible for scientific inquiries

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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