

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of changes of dental plaque as well as caries in maxillary incisors after using of Silver Diamine Fluoride and coconut oil among children with Early Childhood Caries

Protocol summary

Study aim

Changes of dental plaque and caries after using of Silver Diamine Fluoride and coconut oil among children with Early Childhood Caries

Design

60 children under 6 years of age are randomly selected and divided into 3 groups with a table of random numbers. The study is single blinded, and patients do not know what substance they're using.

Settings and conduct

Patients do not know what substance is used for them. The place of study is in Kerman Dental School. On the first and thirtieth day of the study, plaque samples and photographs are taken from patients.

Participants/Inclusion and exclusion criteria

Complete physical health, Proper cooperation of the child and parents, Do not take antibiotics, Do not use mouthwash or fluoride gel or xylitol chewing gum for 1 month before the start of the study, Absence of deep caries in the anterior maxillary teeth with the possibility of pulpal involvement, No allergies to metals, especially silver and coconut oil and products with coconut essential oil

Intervention groups

The first group is as a control and no substance is used for them. The second group uses the 30% SDF (Biodinamica) on the first and fifteenth day of the study by insulating it with a cotton roll and cleaning the teeth with gauze and a drop of the substance is applied to the teeth. Then wait 1-3 minutes. For the third group, coconut oil is used once a day for four weeks. The area is isolated with a cotton roll, then the teeth are cleaned with sterile gauze and then some coconut oil is applied on the teeth.

Main outcome variables

Bacterial changes of dental plaque
Changes in the clinical appearance of teeth

General information

Reason for update

Acronym

"ECC" "SDF"

IRCT registration information

IRCT registration number: **IRCT20201202049571N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Marzieh Pirzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9021

Email address

far.pirzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2021-02-08, 1399/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Ethics committee
Evaluation of changes of dental plaque as well as caries in maxillary incisors after using of Silver Diamine Fluoride and coconut oil among children with Early Childhood Caries	Name of ethics committee Ethics committee of Kerman University of Medical Sciences
Public title	Street address Jahad blvd - Ebnesina avenue
Changes of caries after using of Silver Diamine Fluoride and coconut oil	City Kerman
Purpose	Province Kerman
Prevention	Postal code 7618759689
Inclusion/Exclusion criteria	Approval date 2020-11-30, 1399/09/10
Inclusion criteria: Complete physical health Proper cooperation of the child and parents	Ethics committee reference number IR.KMU.REC.1399.479
Exclusion criteria: Do not take antibiotics Do not use mouthwash or fluoride gel or xylitol chewing gum for 1 month before the start of the study Absence of deep caries in the anterior maxillary teeth with the possibility of pulpal involvement No allergies to metals, especially silver and coconut oil and products with coconut essential oil	Health conditions studied
Age From 2 years old to 6 years old	1
Gender Both	Description of health condition studied Decay
Phase N/A	ICD-10 code
Groups that have been masked	ICD-10 code description
Participant	Primary outcomes
Sample size Target sample size: 60	1
Randomization (investigator's opinion) Randomized	Description Changes in dental plaque bacteria
Randomization description Simple random sample, Individual, Random number tables	Timepoint The first and thirtieth day
Blinding (investigator's opinion) Single blinded	Method of measurement Catalase test and fermentation of mannitol and sorbitol
Blinding description Each person has a specific number that is divided into 3 groups based on a table of random numbers. Participants have no information about the use of the material and the material is removed from the same container and consumed in the same way and the presence time of the groups does not interfere.	2
Placebo Not used	Description Appearance changes
Assignment Parallel	Timepoint The first and thirtieth day
Other design features	Method of measurement ICDAS code
Secondary Ids	Secondary outcomes
empty	empty
Ethics committees	Intervention groups
	1
	Description Intervention group 1: The second group on the first and fifteenth day, 30% SDF (Biodinamica) is used in isolation with a cotton roll and to prevent the lips and saliva from hitting the teeth. The teeth are cleaned with gauze and then a drop of the substance is applied to the teeth by

the applicator. The excess liquid is removed from the tooth surface with gauze or cotton and then wait for 1-3 minutes.

Category

Prevention

2

Description

Intervention group 2: Coconut oil is used once a day for four weeks. The area is isolated with a cotton roll, then the teeth are cleaned with sterile gauze and then some coconut oil is applied on the teeth with an applicator so that the teeth are completely oiled.

Category

Prevention

3

Description

Control group: No substance is used for them

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Dental School

Full name of responsible person

Marzieh Pirzadeh

Street address

Shafa street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Marzieh Pirzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Shafa Street

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available