Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of metanolic green tea، green coffee extract and chlorhexidine and on the salivary Streptococcus mutans ٱn preschool children with early childhood caries by the PCR

Protocol summary

Study aim

Determination the effect of metanolic green tea، green coffee extract and chlorhexidine on Streptococcus mutans in preschool children with early childhood caries by the PCR

Design

In this clinical trial study, there will be 90 children aged 4-6 who will be matched for demographic data. Children are randomly divided into 3 groups of 30 people and assigned a code to each participants. ----------

Settings and conduct

Ғirst explain aims to parents, thenwritten informed consent is taken. A questionnaire including the demographic data of the child (age, sex, history of drug use, history of systemic disease, etc.) is also completed.Then, how to observe oral hygiene and brushing explain to all parents and wanted brush without toothpaste to their children for 2 days.During study, dont use gums containing Xylitol and any type of mouthwashes containing chlorhexidine and flouride. Upon completion of the two-day period, Which is considered as a washout period, children are randomly divided into 3 groups of 30 people. After taking saliva sample,too determining Streptococcus mutans, transfer samples to labrator

Participants/Inclusion and exclusion criteria

The entering criteria including children without any sysytemic disease and during the past month dont take antibiotic and topical flouride and dont have any orthodontic appliance. dont take gums containing Xylitol and any mouthmoush or gel containing flouride at least 3 weeks before study, dont have any soft tissue lesion in their mouth and do not have active and severe periodontal disease.

Intervention groups

Chlorhexidine, Green Tea and Green Coffee

Main outcome variables

Streptococcus mutans

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20171020036896N3**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of metanolic green tea، green coffee extract and chlorhexidine and on the salivary Streptococcus mutans ٍin preschool children with early childhood caries by the PCR

Public title

The effect of Green tea, Chlorhexidine and green coffee extract on salivary Streptococcus mutans

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Preschoolers aged 4 to 6 years

Exclusion criteria:

Usage of gum containing xyllitol Soft tissue lesion in the mouth Use orthodontic appliances The presence of systemic disease Take antibiotics and topical fluoride over the past month Presense of active and severe periodontal disease

Age

From **4 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization or unrestricted method will be used and randomization unit is Individual .we will use from Roll of a die from the methods of simple randomization because there are 3 groups in this study that actually the tool of randomization is dice. So the numbers 1 and 2 are for the first group (chlorhexidine) 3 and 4 for the second group (green coffee) and 5 and 6 for the third (green tea). The next step Allocation concealment will be done, In such a way that the allocated group is not known before the assignment of the individual. To achieve this goal, a non-transparent, sealed, random sequence envelope is used . In this way, the statistical specialist will provide 90 envelopes and each of the randomly generated links will be recorded on a card and the cards are arranged in the envelopes . In order to maintain a random sequence, the numbering of envelopes on the outer surface is done in the same order. Finally, the envelops are enclosed and placed in the box, respectively. At the time of the implementation of the study, according to the order of entry of eligible participants, one of the envelopes is opened respectively and will determine the group assigned to that participant. In this study, the assistant of Pediatric Dentistry examines the participants in terms of inclusion and exclusion criteria. Randomization methods are done by an statistical specialist and performance of the study is done by a trained dental student.

Blinding (investigator's opinion)

Double blinded

Blinding description

Because all the materials are in the same consistency gel, in a uniform shape and color, considering the informed consent, participants are unaware of material. Outcome evaluator, who performs PCR, is also unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethic Committee of kerman University of Medical Sciencess

Street address

Vice-Chancellor for Research, Building of Kerman University of Medical Sciences, Tahmasbabad cross, Jahad Street

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2017-12-24, 1396/10/03

Ethics committee reference number

IR.KMU.REC.1395.553

Health conditions studied

1

Description of health condition studied

Streptococcus mutans

ICD-10 code

k02

ICD-10 code description

پوسیدگی دندانی

Primary outcomes

1

Description

Streptococcus mutans

Timepoint

30 minutes and 1 week later application of interventions

Method of measurement

PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Green tea methanolic extract 20%, for 30 minutes and 1 week after saliva taking from 4 to 6 year old children, 1 cc gel with a syringe and a cotton swab is applied to all teeth of the child.

Category

Prevention

2

Description

Intervention group: Green coffee 10% , for 30 minutes and 1 week after saliva taking from 4 to 6 year old children, 1 cc gel with a syringe and a cotton swab is applied to all teeth of the child.

Category

Prevention

3

Description

Control group: Chlorhexidine 0.2% , 30 minutes and 1 week after saliva taking from 4 to 6 year old children, 1 cc gel with a syringe and a cotton swab is applied to all teeth of the child.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشکده دندانپزشکی کرمان بخش تخصصی کودکان

Full name of responsible person

Dr Fatemeh sadat Sajadi

Street address

Pediatric department, School of Dentistry,Shafa street

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

Sajadi@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Tahmasebabad Crossing, Deputy of Research and Technology University

City

kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

kmu_research@yahoo.com

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

60

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

Dr Hamidreza Poureslami

Position

Professor, Faculty of dentistry for children, part of Kerman,

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Pediatric Department, School of Dentistry, Shafa street, Kerman

City

kerman

Province
Kerman
Postal code
7618759689
Phone
+34 32119021
Email
poureslami@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh sadat Sajadi
Position
Associate Professor of Pediatric Dentistry
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Pediatric Department, School of Dentistry, Shafa street, Kerman
City
کرمان
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Fax
Email
sajadi@kmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh sadat Sajadi
Position
Associate Professor of Pediatric Dentistry
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shafa Street, Faculty of Dentistry, Department of pediatrics
City
kerman
Province
Kerman
Postal code
7618759689
Phone
+34 32119021
Fax
Email
Sajadi@kmu.ac.ir
Web page address

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After this study, data and statistical analysis data are available to all.
When the data will become available and for how long
After completing the research plan for 5 years of information dissemination
To whom data/document is available
All Researchers and Faculty Members
Under which criteria data/document could be used
In order to conduct new researches
From where data/document is obtainable
Department of Research and Technology Faculty
What processes are involved for a request to access data/document
Submitting a request to the person responsible for collecting documentation of research projects at the Department of Research and and technology Faculty
Comments