Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the antibacterial effectiveness of thymes and chamomile extract and chlorhexidine on the salivary Streptococcus mutans of preschool childrens with early childhood caries by the quantitative Real Time PCR

Protocol summary

Study aim

Comparison of the antibacterial effectiveness of thymes and chamomile extract and chlorhexidine on the salivary Streptococcus mutans of preschool childrens with early childhood caries by the quantitative Real Time PCR

Design

In this clinical trial study, there will be 90 preschool children aged 4-6 who will be matched from demographic data. Children are randomly divided into 3 groups of30 person and each participant assigned a code.

Settings and conduct

First the aims of the study explain to the parents, then written 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, the methods of oral hygiene and brushing explain to all parents and wanted to brush the teeth of their children without toothpaste for 2 days. also it is emphasized that during the study, the children do not use gums containing Xylitol and any type of mouthwashes containing chlorhexidine and fluoride. Upon completion of the two-day period, Which is considered as a washout period, children are randomly divided into 3 groups of 30 person. then from the participant children will take the sample of saliva and transfer to laboratory for determining the amount of Streptococcus mutans.

Participants/Inclusion and exclusion criteria

The inclusion criteria including preschool children aged 4 to 6 years that have at least dmft 4 and 3 dental caries in their mouth.exclusion criteria including preschool children with sysytemic disease , during the past month take antibiotic and topical flouride and have orthodontic appliance, who take gums containing Xylitol and mouthwash or gel containing flouride at least 3 weeks before study, who have soft tissue lesion in their mouth and have active and severe periodontal disease.

Intervention groups

Intervention group 1: thymes extract 5% , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child. Intervention group 2: chamomile extract 5% , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child. Control group1: cholorhexidine 0.02 % , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child.

Main outcome variables

Streptococcus mutans,

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20171020036896N4**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **retrospective**

Last update: **2018-03-09, 1396/12/18**
Update count: **0**

Registration date

2018-03-09, 1396/12/18

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 antibacterial effectiveness of thymes and chamomile extract and chlorhexidine on the salivary Streptococcus mutans of preschool childrens with early childhood caries by the quantitative Real Time PCR

Public title

The antibacterial effectiveness of thymes and chamomile extract and chlorhexidine and on the salivary Streptococcus mutans

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Preschoolers aged 4 to 6 years having at least dmft 4 having at least 3 dental caries

Exclusion criteria:

Usage of gum containing xyllitol ، any type of mouthwash or gel of fluoride at least 3 weeks before the study Soft soft tissue lesion in the mouth Useing orthodontic appliances Take antibiotics and topical fluoride over the past month Active and severe periodontal disease The presence of systemic disease

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

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 (thymes) and 5 and 6 for the third (chamomile). 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 that what materials is used for. 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, kerman,iran

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
ICD-10 code description

Primary outcomes

1

Description
Streptococcus mutans
Timepoint
before application and 30 minutes and 1 week after application of interventions
Method of measurement
quantitative real time PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: thyme extract 5% , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child.
Category
Prevention

2

Description
Intervention group2: Chamomile extract 5% , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child.
Category
Prevention

3

Description
Control group1: cholorhexidine 0.02 % , 30 minutes and 1 week after first salivary sampling from 4 to 6 year old children, 1 cc gel measured with a syringe and with a cotton swab is applied to all teeth of the child.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Department of Dentistry University of Kerman
Full name of responsible person
Dr Fatemeh sadat Sajadi
Street address
Pediatric department, School of Dentistry,Shafa street
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kerman
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7618759689
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+98 34 3211 9021
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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
No.1 Ave,Tahmasebabad Intersection, Research - Vice Chancellor of Kerman University of Medical Science
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7619813159
Phone
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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

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Pediatric Department, School of Dentistry, Shafa street, Kerman

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Dr Fatemeh sadat Sajadi

Position
Associate Professor of Pediatric Dentistry

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because the study data do not have any other scientific application.

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