# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the antibacterial effect of metanolic green tea extract , Teucrium Polium plant and chlorhexidine gel on the salivary streptococcus mutans in preschool children with early childhood caries by the PCR

## Protocol summary

**Study aim**
Determination the antibacterial effect of metanolic green tea، Teucrium Polium plant and chlorhexidine gel 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**
First explain aims to 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, how to observe oral hygiene and brushing explain to all parents and wanted brush without toothpaste to their children for 2 days.During study, don't 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 people. After taking saliva sample , transfer samples to laboratory for determining Streptococcus mutans.

**Participants/Inclusion and exclusion criteria**
The inclusion 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 Teucrium Polium plant

**Main outcome variables**
Streptococcus mutans

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20171020036896N5**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **prospective**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

**Registration date**
2018-04-04, 1397/01/15

**Registrant information**
**Name**
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 32119023
**Email address**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2018-04-21, 1397/02/01
**Expected recruitment end date**
2018-06-22, 1397/04/01
**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the antibacterial effect of metanolic green tea extract , Teucrium Polium plant and chlorhexidine gel on the salivary streptococcus mutans in preschool children with early childhood caries by the PCR

**Public title**
the antibacterial effect of metanolic green tea extract , Teucrium Polium plant and chlorhexidine gel on the salivary streptococcus mutans in preschool children
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Preschool children aged 4 to 6 years
**Exclusion criteria:**
Usage of gum containing xyllitolSoft tissue lesion in the mouthUse orthodontic appliancesThe presence of systemic diseaseTake antibiotics and topical fluoride over the past monthPresense 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
- 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 (Teucrium Polium) 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**
Ethics committee of Kerman University of Medical Sciences
**Street address**
Vice-Chancellor for Research, Kerman University of Medical Sciences, Tahmasbabad cross, Jahad Street,Kerman
**City**
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**Province**
Kerman
**Postal code**
7619813159
**Approval date**
2018-04-03, 1397/01/14
**Ethics committee reference number**
IR.KMU.REC.1395.681

## Health conditions studied

### 1

**Description of health condition studied**
Streptococcus mutans
**ICD-10 code**
K02
**ICD-10 code description**
Dental caries

## Primary outcomes

**1**

**Description**
Streptococcus mutans
**Timepoint**
before application and 30 minutes and 1 week after application of interventions
**Method of measurement**
PCR test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group:Green tea methanolic extract 20%, 1 cc gel with a graded syringe is measured and with a cotton swab is applied to the teeth of the child.
**Category**
Prevention

**2**

**Description**
Intervention group: Teucrium Polium plant 20%, 1 cc gel with a graded syringe is measured and with a cotton swab is applied to the teeth of the child.
**Category**
Prevention

**3**

**Description**
Control group: Chlorhexidine 0.2%,1 cc gel with a graded syringe is measured and with a cotton swab is applied to the teeth of the child.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Pediatric Department of Dental school of Kerman University of Medical Sciences
**Full name of responsible person**
Fatemeh sadat Sajadi
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
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 of pediatric department, Faculty of dentistry ,
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Specialist
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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)**
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**
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