# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative study on the effect of oral mucosal tea and green tea gel on Streptococcus mutans and lactobacilli saliva in adolescents aged 12 to 18 years

## Protocol summary

**Summary**

To conduct this study, 30 adolescents aged 12 to 18 years old, who themselves and their parents sign a informed consent form, are selected according to entry and exit criteria. A salivary specimen is sent to the laboratory to count the colony of Streptococcus mutans and lactobacillus. The randomization was performed based on the amount of Streptococcus mutans and lactobacilli saliva and individuals are randomly assigned into two groups of random numbers. . The goal is to measure the amount of these microorganisms at the beginning of the study in two groups. For two weeks, a mouthpiece group is given to another group of green tea gel. After the end of two weeks, a saliva sample is taken and a colony count is taken. After the washout period of 4 weeks, the first phase process is performed in two groups in reverse order. The results are analyzed by independent t-test and paired t-test.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017090135652N2**
Registration date: **2017-09-25, 1396/07/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-09-25, 1396/07/03

**Registrant information**

**Name**

maryam hajahmadi

**Name of organization / entity**

Isfahan university of medical sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Investigator

**Expected recruitment start date**

2017-05-22, 1396/03/01

**Expected recruitment end date**

2017-07-23, 1396/05/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study on the effect of oral mucosal tea and green tea gel on Streptococcus mutans and lactobacilli saliva in adolescents aged 12 to 18 years

**Public title**

Influence of Green Tea on the Prevention of Caries in Adolescents

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Adolescents aged 12 to 18 years who have signed the informed consent form and are considered systemically healthy by the individual and his or her parents. Do not eat xylitol chemically at least three weeks before and do not use during the study. They also received no systemic antibiotics and topical fluoride therapy for 4 weeks or

more. Oral hygiene is good and brushing twice a day. Active dental caries (which have cavities and are symptomatic and have pain) and do not have periodontal disease and gingivitis. Exit criteria: Children who received systemic antibiotics and topical fluoride therapy 4 weeks ago, those with systemic disease, the presence of cavity caries or active and untreated periodontal disease, the presence of an orthodontic brace or fixed or movable prosthesis

**Age**
From **12 years** old to **18 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **30**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Isfahan University of Medical Sciences

**Street address**
Faculty of Dentistry, Isfahan University of Medical Sciences,Hezarjerib street ,Isfahan

**City**
Isfahan

**Postal code**

**Approval date**
2017-01-27, 1395/11/08

**Ethics committee reference number**
396177

## Health conditions studied

**1**

**Description of health condition studied**
dental caries

**ICD-10 code**
K00-K14

**ICD-10 code description**
K00-K14

## Primary outcomes

**1**

**Description**
streptococcus mutans and lactobacillus

**Timepoint**
Before intervention

**Method of measurement**
microbiology and withculicativating bacteria

## Secondary outcomes

**1**

**Description**
decrease or elimination of streptococcus mutans and lactobacillus

**Timepoint**
two weeks after intervention

**Method of measurement**
microbiology and with cultivating bacteria

## Intervention groups

**1**

**Description**
Mouthwash and gel use

**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Isfahan University of Medical Sciences, Faculty of Dentistry, Pediatrics Department

**Full name of responsible person**

**Street address**

**City**
Isfahan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research , Isfahan University of Medical Sciences

**Full name of responsible person**
Leila sarrami

**Street address**
Esfahan, Faculty of Dentistry, Department of

Pediatrics

**City**

Esfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research , Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr.Maryam Haji ahmadi

**Position**

Assistant Professor

**Other areas of specialty/work**

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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*