

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

Phone

+98 31 3266 2236

Email address

maryam_hajahmadi@dnt.mui.ac.ir

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, Hezarjerd 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 withcultivating 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

Street address

Faculty of Dentistry, Department of Pediatrics

City

Isfahan

Postal code

Phone

+98 31 3624 2155

Fax

Email

maryam_hajahmadi@dnt.mui.ac.irl.sarrami.18@gmail.com

Web page address

Person responsible for scientific 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

Street address

Faculty of Dentistry, Department of Pediatrics

City

Isfahan

Postal code

Phone

+98 31 3624 2155

Fax

Email

maryam_hajahmadi@dnt.mui.ac.irl.sarrami.18@gmail.com

Web page address

Person responsible for updating data

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

Street address

Esfahan, Faculty of Dentistry, Department of Pediatrics

City

Esfahan

Postal code

Phone

+98 31 3624 2155

Fax

Email

l.sarrami.18@gmail.com

Web page address

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