

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of L-arginine toothpaste and fluoride toothpaste on Streptococcus mutans in orthodontic patients: PCR based-method, single center, triple blind randomized clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the effects of L-arginine toothpaste on streptococcus mutans in orthodontic patients.

Design

A single-center, concealed, randomized, triple blind clinical trial with the control group

Settings and conduct

72 Participants will be recruited from orthodontic patients attending the orthodontic clinic at the Dental faculty of Shiraz University of Medical Science Block randomization method will be used with block length = 6 to allocate patients to two study groups with a 1:1 ratio: fluoride toothpaste group (control) and L-arginine toothpaste group (experimental). All toothpaste will be spilled into identical tubes that will be color coded by, so the clinician who assigns the intervention, the patients, laboratory technician, and the statistician will be all blind to the treatment groups. Biofilm samples will be collected at 2 times: at the beginning of the study (T0) and after 30 days (T1). Polymerase chain reaction will be used to analyses the biofilm samples.

Participants/Inclusion and exclusion criteria

15-30 year-old patients with fixed orthodontic appliance, who have signed the informed consent form.

Intervention groups

1- Control group: Fluoride toothpaste twice a day
2- Experimental group 2: Arginine toothpaste twice a day

Main outcome variables

Amount of streptococcus mutans in biofilm samples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181121041713N2**

Registration date: **2019-12-24, 1398/10/03**

Registration timing: **retrospective**

Last update: **2019-12-24, 1398/10/03**

Update count: **0**

Registration date

2019-12-24, 1398/10/03

Registrant information

Name

neda babanouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 0801

Email address

babanouri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of L-arginine toothpaste and fluoride toothpaste on Streptococcus mutans in orthodontic patients: PCR based-method, single center, triple blind randomized clinical trial

Public title

Effects of L-arginine toothpaste in orthodontic patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Both male and female subjects Age between 15 and 30 years Permanent dentition Good general health (no significant medical history or medication during the last month) No anti-inflammatory or antibiotic medications taken in the month before the study No chewing gum or mouthwash use in the last week and during the study Habit of brushing twice daily with fluoride toothpaste No open or untreated caries lesions or gingival inflammation

Exclusion criteria:

Diseases and medications that would be likely to affect dental biofilm Poor oral hygiene, Active periodontal disease Sever crowding of anterior teeth or sever malposition of lateral incisor that would be likely to interfere with cleaning of tooth surface Smoking History of mouth breathing

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

All toothpaste will be spilled into identical tubes that will be color coded by the first investigator (NB), so the clinician who assigns the intervention, the patients, laboratory technician, and the statistician will be all blind to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

School of Dentistry, Qom Abad, Ghasrodasht St.

City

Shiraz

Province

Fars

Postal code

7195615878

Approval date

2019-08-23, 1398/06/01

Ethics committee reference number

IR.SUMS.DENTAL.REC.1398.58

Health conditions studied**1****Description of health condition studied**

Amount of streptococcus mutans in dental biofilm

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Amount of streptococcus mutans in dental biofilm

Timepoint

T0: at the beginning of the study, T1 after 30 days

Method of measurement

Real-time polymerase chain reaction will be used to analyses the biofilm samples

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patients will be asked to brush their teeth twice a day with toothpaste containing 8% arginine.

Category

Prevention

2**Description**

Control group: : Patients will be asked to brush their teeth twice a day with fluoride toothpaste

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic Clinic of Shiraz Dental Faculty

Full name of responsible person

Dr. Mahtab Memarpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemy

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

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

Shiraz University of Medical Sciences

Full name of responsible person

Neda Babanouri

Position

Assistant Professor

Latest degree

Specialist

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)**

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

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