Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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.DENTAI.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
Street address
School of Dentistry, Qom Abad, Ghasrodasht St.
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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
Street address
6th Floor, Central building of Shiraz University of Medical Sciences Zand St.
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7134814336
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ghasemiy@sums.ac.ir

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