Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The anti-bacterial effect on streptococcus mutans of chitosan mouth rinse in patients wearing orthodontic removable appliance

Protocol summary

Study aim
Using anti-bacterial effect of chitosan mouth rinse on streptococcus mutans in patients wearing orthodontic removable appliance

Design
Randomized, controlled, clinical trial

Settings and conduct
Babol Dentistry University

Participants/Inclusion and exclusion criteria
20 patients (10 females and 10 males) 9 to18 years old referring to Babol orthodontics department. None of patients suffer from active caries, periodontal and systematic disease. None of patients use antibiotics in the last three months . We exclude patients with past fixed orthodontic treatment and any kind of dental treatment during study.

Intervention groups
The Chitosan with low (75%<DD<85%,MW 107 kDa) and high (75%<DD,MW 624 kDa) molecular weight which is produced by Sigma-Aldrich, St.Loius, USA was used for producing mouthwash. The mouthwash was produced with the 0.4% v/v dose and PH=5 of Chitosan. This compound consisted of 0.5% (W/V) NaCl salt, 1% (W/V) of Arabic gum stabilizer, and 5% (W/V) of Mannitol. After the complete solution, food flavor and oral dyes were added with a dose of 0.1% (V/V). The mouthwash which lacked the Chitosan was used as Placebo, containing the materials as mentioned above with the same pH, except Chitosan. The swab samples were made for the buccal area of upper right first molar. . Each sample was placed inside a tube of 1 mL brain - heart infusion and then cultured in the Mitis salivarius agar medium. After 48h of incubation at 37℃, the Streptococcus mutans colonies were counted using the digital colony counter

Main outcome variables
streptococcus mutans colonies on mitis salivarius agar medium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190410043228N2**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **retrospective**

Last update: **2021-02-08, 1399/11/20**
Update count: **0**

Registration date
2021-02-08, 1399/11/20

Registrant information

Name
mojan madani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-05, 1399/04/15

Expected recruitment end date
2020-08-05, 1399/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The anti-bacterial effect on streptococcus mutans of chitosan mouth rinse in patients wearing orthodontic removable appliance

Public title
The anti-bacterial effect on streptococcus mutans of chitosan mouth rinse
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
wearing removable orthodontics appliance without expansion screw patients from 9 to 18 years old
Exclusion criteria:
active caries and periodontal disease Suffering from a systemic disease antibiotic consumption in the last three months past fixed orthodontics or any kind of dental treatment during clinical study
Age
From **9 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Replacement blocks will be utilized for the purpose of randomization (the number of blocks based on the sample volume in the study). In this regard, "A" represents experimental group and “B” represents control group. Two individual outcomes AB and BA are possible. Moreover, it will be assumed that AB replaces even outcomes from the data table and BA replaces odd numbers
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Comittee of Babol University of Medical sciences
Street address
Babol Dentistry University, Ganj Afroz str.
City
Babol
Province
Mazandaran
Postal code
4774547176
Approval date
2019-06-09, 1398/03/19
Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.117

Health conditions studied

1

Description of health condition studied
The anti-bacterial effect on streptococcus mutans of chitosan mouth rinse
ICD-10 code
B95.4
ICD-10 code description
Other streptococcus as the cause of diseases classified elsewhere

Primary outcomes

1

Description
counting of streptococcus mutans colonies
Timepoint
Before intervention, 1 month later
Method of measurement
using the digital colony counter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will learn oral hygiene instructions including brushing (modified Bass) and flossing the teeth. All patients were given time schedule for one month, in which they had to check it after each usage. All patients needed removable orthodontic appliances without expansion screw. A new removable orthodontic appliance was produced with Acroplus acrylic resin in the faculty laboratory a week after the healtheducation.The Chitosan with low (75%<DD<85%,MW 107 kDa) and high (75%<DD,MW 624 kDa) molecular weight which is produced by Sigma-Aldrich, St.Loius, USA was used for producing mouthwash. The mouthwash was produced with the 0.4% v/v dose and PH=5 of Chitosan. This compound consisted of 0.5% (W/V) NaCl salt, 1% (W/V) of Arabic gum stabilizer, and 5% (W/V) of Mannitol. After the complete solution, food flavor and oral dyes were added with a dose of 0.1% (V/V). The swab samples were made

for the buccal area of upper right first molar. Each sample was placed inside a tube of 1 mL brain - heart infusion and then cultured in the Mitis salivarius agar medium. After 48h of incubation at 37℃, the Streptococcus mutans colonies were counted using the digital colony counter

Category

Treatment - Drugs

2

Description

Control group: Patients will learn oral hygiene instructions including brushing (modified Bass) and flossing the teeth. All patients were given time schedule for one month, in which they had to check it after each usage. All patients needed removable orthodontic appliances without expansion screw. A new removable orthodontic appliance was produced with Acroplus acrylic resin in the faculty laboratory a week after the healtheducation. The mouthwash was produced with PH=5. This compound was consisted of 0.5% (W/V) NaCl salt, 1% (W/V) of Arabic gumstabilizer, and 5% (W/V) of Mannitol. After the complete solution, food flavor and oral dyes were added with the dose of 0.1% (V/V). Placebo mouthwashes were used (7 times in a week, each time for 20 seconds). The swab samples were made for Palatal area. Each sample was placed inside a tube of 1 mL brain - heartinfusion and then cultured in the Mitis salivarius agar medium. After 48h of incubation at 37℃,the Streptococcus mutans colonies were counted using the digital colony counter.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol Dentistry University
Full name of responsible person
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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

Babol 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
Arak University of Medical Sciences
Full name of responsible person
Mojan Madani
Position
Assistant professor
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
all data without recognizing participants in research
When the data will become available and for how long
2020 year
To whom data/document is available
researchers
Under which criteria data/document could be used
in future researches
From where data/document is obtainable
published article
What processes are involved for a request to access data/document
referring to published article
Comments