

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 to 18 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. Louis, 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°C, 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

Country

Iran (Islamic Republic of)

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Email address

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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 Committee 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 health education. 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. Louis, 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°C, 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 health education. The mouthwash was produced with PH=5. This compound was 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 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 - heart infusion and then cultured in the Mitis salivarius agar medium. After 48h of incubation at 37°C, 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

Mojan Madani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Other areas of specialty/work

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Specialist
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Person responsible for updating data

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Specialist
Other areas of specialty/work

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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