Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of chitosan mouthwash and chitosan-free mouthwash on plaque and gingival indices of patients with fixed orthodontic retainer

Protocol summary

Study aim
Evaluation of the effect of Chitosan mouthwash on plaque and gingival indices in patients with fixed orthodontic retainer

Design
A clinical trial with a control group, with a parallel group design, double-blind, randomized, phase 3 on 22 patients, the block randomization method was used for randomization and the selection of these blocks will be using a random number table.

Settings and conduct
Candidated patients to receive fixed orthodontic retainer at Mehregan Arak Dental Clinic are selected based on the conditions of entry into the study and after placing the fixed orthodontic retainer, they will be given hygiene training on how to use dental floss and toothbrush, as well as how to use mouthwash. The study will be double-blind, in which the patients and the researcher will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People who do not have dental caries, disease and periodontal surgery and have not used antibiotics in the last three months. Non-inclusion criteria: infection in the last six months, diabetes, smoking, alcohol consumption, pregnancy, cancer, drug use that affects periodontal conditions, and systemic conditions requiring anti-prophylaxis.

Intervention groups
Intervention group: Chitosan mouthwash (twice a day) will be used. Control group: mouthwash without chitosan (2 times a day) will be used.

Main outcome variables
Probe depth above 3 mm; Bleeding on probing; gingival index; plaque index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220726055561N1**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-22, 1401/09/01**
Update count: **0**

Registration date
2022-11-22, 1401/09/01

Registrant information

Name
Arefe Diba

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3223 3311

Email address
arefe.diba7@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-06, 1401/08/15

Expected recruitment end date
2023-02-04, 1401/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of chitosan mouthwash and chitosan-free mouthwash on plaque and gingival indices of patients with fixed orthodontic retainer

Public title
The effect of chitosan mouthwash on plaque and gingival indices in patients with fixed orthodontic retainer
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
No dental caries No disease and periodontal surgery not used antibiotics in the last three months
Exclusion criteria:
Infection in the last six months diabetes smoking Consumption of alcohol Pregnancy Cancer Taking medications that affect periodontal conditions Systemic conditions require antibiotic prophylaxis prior to periodontal examination Patients who have a history of fixed orthodontic treatment in the past or any dental treatment during the study
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization method is used. For this purpose, using blocks of size 4 including AABB, ABAB, BBAA, etc. is used and selected. These blocks will be selected using a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double-blind, in which the patients and the researcher, who is a dentist trained by periodontics specialist will be blind. In this way, patients and researchers in both mouthwash groups will not notice the difference between the mouthwashes due to the similar appearance of the mouthwash bottles. The result information is also provided by a dentist trained by a periodontics specialist who does not know which group the patient is in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
No. 40 , Yaas 5 Alley, Shahid Mahmoodabadi Ave , Shahid Rajayee Ave
City
Arak
Province
Markazi
Postal code
3813876831
Approval date
2022-08-28, 1401/06/06
Ethics committee reference number
IR.ARAKMU.REC.1401.052

Health conditions studied

1

Description of health condition studied
Chronic Gingivitis
ICD-10 code
K05.1
ICD-10 code description
Chronic gingivitis

Primary outcomes

1

Description
probe depth above 3 mm
Timepoint
Probe depth measurement at the beginning of the study and 30 days after using the mouthwash
Method of measurement
With a Michigan calibrated periodontal probe

2

Description
bleeding on probing
Timepoint
Measurement of bleeding during probing at the beginning of the study and 30 days after using the mouthwash
Method of measurement
With a Michigan calibrated periodontal probe

3

Description
gingival index
Timepoint
Measurement of gingival index at the beginning of the study and 30 days after using the mouthwash
Method of measurement
Observational

4

Description
plaque index
Timepoint
Measuring the plaque index at the beginning of the study and 30 days after using the mouthwash
Method of measurement
he degree of staining of dental plaque after using Fuchsin tablets

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Chitosan mouthwash (2 times a day) will be used. Patients should rinse 10cc of mouthwash for 60 seconds at a time and do not consume anything until 30 minutes later .Low molecular weight (75% <DD <85%, MW 107 kDa) and high (75% <DD, MW 624 kDa) chitosan produced by Sigma-Aldrich, St. Louis, USA, for the production of mouthwash will be. Chitosan mouthwash will be produced with 0.4% v / v dose and PH = 5. This compound will be composed of 0.5% (W / V) NaCl salt, 1% (W / V) of Arabic gum stabilizer and 5% (W / V) of Mannitol. After complete solution, food flavor and food coloring are added at a dose of 0.1% (V / V).
Category
Treatment - Drugs

2

Description
Control group: mouthwash without chitosan (2 times a day) will be used. Patients should rinse 10cc of the mouthwash for 60 seconds and not consume anything for 30 minutes after that. Chitosan-free mouthwash with PH=5 will be produced. This composition will be formed with 0.5% (W/V) NaCl salt, 1% (W/V) of Arabic gum stabilizer and 5% (W/V) of Mannitol. After the complete solution, food flavoring and food colors are added at a dose of 0.1% (V/V). Chitosan-free mouthwash is used as a placebo and contains the ingredients mentioned above with the same pH; It is prepared without the main ingredient, which is chitosan. This mouthwash is prepared from the same company from which the original mouthwash is purchased. The container containing the mouthwash and the witness will be similar in appearance so that patients do not notice the difference.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehrgan Dental Clinic
Full name of responsible person
Mehdi Mikalani
Street address
Shahid Beheshti Street
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3848170001
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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Basij Square
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Postal code
7000238481
Phone
+98 86 3417 3532
Email
alikamaliir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Arak 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

Arefe Diba

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Dental student

Latest degree

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Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable