

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

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

Protocol summary

Study aim

Evaluation of the effect of Chitosan mouthwash on plaque and gingival indices in fixed orthodontic patients

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

All patients attending Arak Mehrgan dental clinic who are undergoing orthodontic treatment will be selected. They will be given hygiene education to use dental floss and toothbrush. 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: **IRCT20220611055141N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Amirmohammad Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-11-06, 1401/08/15

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 fixed orthodontic patients

Public title

The effect of chitosan mouthwash on plaque and gingival indices in patients with fix orthodontic

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
Arak University of Medical Sciences, Payambar Azam Complex, Sardasht

City
arak

Province
Markazi

Postal code
3848170002

Approval date
2022-05-15, 1401/02/25

Ethics committee reference number
IR.ARAKMU.REC.1401.052

Health conditions studied

1

Description of health condition studied

PD (Probe Depth); BOP (Probe on Bleeding); PI (Plaque Index); GI (Gingival Index)

ICD-10 code

ICD-10 code description

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

The 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

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Shahid Beheshti Street

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

Amirmohammad Jafari

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Amirmohammad Jafari

Position

Dental student

Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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Position

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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