

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of Protact mouthwash (Zataria Multiflora extract) on streptococcus mutans and lactobacillus and gingival indexes in patients undergoing fixed orthodontic treatment

Protocol summary

Study aim

Evaluation of the effect of Protact mouthwash (Zataria Multiflora extract) on Streptococcus mutans and Lactobacillus and gingival indices in patients undergoing fixed orthodontic treatment

Design

In this double-blind clinical trial, 60 eligible patients were randomly divided into three groups of Protact mouthwash (Zataria Multiflora extract), chlorhexidine mouthwash and physiological serum mouthwash (placebo) and they use mouthwash for 21 days.

Settings and conduct

Eligible patients will first undergo sampling to measure the number of Streptococcus mutans and Lactobacillus colonies as well as screening for modified gingival index (MGI) and gingival bleeding index (BI). They were then randomly assigned to one of three study groups and used mouthwash for 21 days. At the end, the above assessment are re-conducted. The mouthwashes as well as the physiological saline, as placebo, are provided in similar plastic containers with same size, so that the patient and the researcher will not be aware of the type of mouthwash.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing fixed orthodontic treatment (including brackets on the anterior and premolars and band on first molar), at least three to five months after orthodontic treatment with proper oral hygiene major exclusion criteria: Existence of immune insufficient disease or systemic diseases, the presence of severe rotation and malposition in teeth, periodontists or active dental caries, pregnancy and lactation, and sensitivity to mouthwash

Intervention groups

Three groups: Protact mouthwash (Zataria Multiflora extract), chlorhexidine mouthwash and physiological saline mouthwash (placebo)

Main outcome variables

Streptococcus mutans and Lactobacilli colony count, Modified gingival index (MGI), and Gingival bleeding Index (BI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190803044423N2**
Registration date: **2019-09-18, 1398/06/27**
Registration timing: **prospective**

Last update: **2019-09-18, 1398/06/27**

Update count: **0**

Registration date

2019-09-18, 1398/06/27

Registrant information

Name

bahareh fatemipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-02, 1398/12/12

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Protact mouthwash (Zataria Multiflora extract) on streptococcus mutans and lactobacillus and gingival indexes in patients undergoing fixed orthodontic treatment

Public title
Evaluation of the effect of Protact mouthwash (Zataria Multiflora extract) on streptococcus mutans and lactobacillus and gingival indexes in patients undergoing fixed orthodontic treatment

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing fixed orthodontic treatment (including brackets on the anterior and premolars and band on first molar) At least three to five months after orthodontic treatment Proper oral hygiene

Exclusion criteria:

Existence of immune insufficient disease or systemic diseases The presence of severe rotation and malposition in the second premolar teeth Existence of periodontitis Existence of active dental caries Smoking and substance use Taking any antibiotics and antifungal medication for several days before starting the study and during the study period Pregnancy and lactation Sensitivity to mouthwash Use of mouthwash in the past month The consumption of drinks containing Zataria Multiflora during the study period Not using the recommended health protocol during the study Do not use mouthwash as instructed during the study period

Age
From **13 years** old to **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple random allocation. In such a way, the required number of cards in each study group labeled A, B, and C is placed in a bag. Upon referral, a eligible case is asked to take one of the cards. Card A will be in the control group (placebo), card B will be in the Protact mouthwash (Zataria Multiflora extract) group and card C will be in the chlorhexidine group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The mouthwashes as well as the physiological serum, as placebo, are provided in similar plastic containers with same size, so that the patient and the researcher will not be aware of the type of mouthwash.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Dr Hesabi Sq.

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Zahedan

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Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.ZAUMS.REC.1398.214

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Streptococcus mutans colony count

Timepoint

At baseline (3 to 6 months after orthodontic treatment) and 21 days after intervention

Method of measurement

Swab specimen culture from cervical enamel of second premolars and central incisors of both mandibles adjacent to brackets

2

Description

Lactobacilli colony count

Timepoint

At baseline (3 to 6 months after orthodontic treatment) and 21 days after intervention

Method of measurement

Swab specimen culture from cervical enamel of second premolars and central incisors of both mandibles adjacent to brackets

3

Description

Modified gingival index (MGI)

Timepoint

At baseline (3 to 6 months after orthodontic treatment) and 21 days after intervention

Method of measurement

The labial/facial surfaces of the gingiva and the interdental papillae of the desired teeth are examined and rated for inflammation from zero (no inflammation) to 4 (severe inflammation)

4

Description

Gingival bleeding Index (BI)

Timepoint

At baseline (3 to 6 months after orthodontic treatment) and 21 days after intervention

Method of measurement

The probe is carefully inserted into the pocket of the desired tooth, gently moving sideways to the wall of the pocket, and scored based on its bleeding time. In case of no bleeding within 30 seconds, score is zero, in case of bleeding within 30 seconds, score is 1 and in case of immediate bleeding, score is 2.

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Protact mouthwash (Zataria Multiflora extract)

Category

Prevention

2

Description

Second Intervention group: Chlorhexidine mouthwash

Category

Prevention

3

Description

Control group: Physiological serum mouthwash

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Bahareh Fatemipour

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Sponsors / Funding sources

1

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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

Zahedan University of Medical Sciences

Proportion provided by this source

40

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
Zahedan University of Medical Sciences
Full name of responsible person
Bahareh Fatemipour
Position
Associate 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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No need.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available