

# 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)

##### Phone

+98 54 3341 4002

##### Email address

fatemipourb@zaums.ac.ir

##### 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.

**City**

Zahedan

**Province**

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

##### **Street address**

East Azadeghan St.

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##### **Postal code**

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+98 54 3342 9519

##### **Email**

Fatemipourb@zaums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Noor Mohammad Bakhshani

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##### **Email**

zaums.research@gmail.com

##### **Web page address**

<http://research.zaums.ac.ir/>

#### **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 scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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