

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the comparative effect of Protact mouthwash (Zataria Multiflora extract) and chlorhexidine on Candida Albicans and gingival indexes in patients undergoing fixed orthodontic treatment

Protocol summary

Gingival index(BI.MGI) Candida albicans number of fung

Study aim

Evaluation of the Effect of Protact Mouthwash(Zataria Mutiflora) and Chlorhexidine on Candida Albicans and Gingival Indices in Patients Under 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 saline mouthwash (placebo) and they use mouthwash for 21 days.

Settings and conduct

Eligible patients will first undergo sampling to measure the number of candida albicans 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, periodontitis or active dental caries, pregnancy and lactation, and sensitivity to mouthwash

Intervention groups

Protact Mouthwash(Zataria Mutiflora) Chlorhexidine Mouthwash physiological saline as plasebo

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190803044423N1**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **prospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **1**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

bahareh fatemipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 comparative effect of Protact mouthwash (Zataria Multiflora extract) and chlorhexidine on Candida Albicans and gingival indexes in patients undergoing fixed orthodontic treatment

Public title

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

Purpose

Supportive

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 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 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

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 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.

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

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Balouchestan Blvd.Zahedan University of Medical science.9816743463

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ZAHEDAN

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.ZAUMS.REC.1398.213

Health conditions studied**1****Description of health condition studied**

Candida albicans number of fungi,gingival index

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Candida albicans number of fungi

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**

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)

3

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

Control group: placebo physiological saline

Category

Placebo

2

Description

Intervention group: protact mouthwash(zataria mutiflora)

Category

Treatment - Drugs

3

Description

Intervention group: Chlorhexidine Mouthwash 0.12%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty Dentistry of Zahedan University of Medical Science

Full name of responsible person

Bahareh Fatemipour

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Azadegan Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Web page address

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

1

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

Orthodontics

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable