Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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 Multilflora 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

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

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

+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 comparative effect of Protact mouthwash (Zataria Multilflora 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 Multilflora 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 Multilflora 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

Street address
Balouchestan Blvd.Zahedan University of Medical science.9816743463

City
ZAHEDAN

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2019-07-28, 1398/05/06

Ethics committee reference number
IR.ZAUMS.REC.1398.213

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
Street address
Azadegan Avenue
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817699693
Phone
+98 54 3341 4002
Email
drfatemib@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noor Mohammad Bakhshani
Street address
Balouchestan Blvd.Zahedan University of Medical Science
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Email
zaums.research@gmail.com
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
Street address
Balouchestan Blvd.Zahedan University Medical Science
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5744
Email
drfatemib@gmail.com

Person responsible for scientific 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
Street address
Balouchestan Blvd.Zahedan University of Medical Science
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5744
Email
drfatemib@gmail.com

Person responsible for updating data

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
Street address
Balouchestan Blvd.Zahedan University of Medical Science
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Email
drfatemib@gmail.com

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