

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### comparative evaluation of the effect of pomegranate mouthrinse and chlorhexidine mouthrinse on severe chronic periodontitis treatment

#### Protocol summary

##### Study aim

This study was performed to compare the effect of pomegranate mouthwash and chlorhexidine mouthwash on clinical improvement of severe chronic periodontitis.

##### Design

A randomized controlled clinical trial with factorial groups, double blind, randomized

##### Settings and conduct

A questionnaire including patient characteristics and inflammatory criteria will be completed by the plan administrator for patients referring to the periosteum department of Zahedan Dental School, where severe chronic periodontitis is diagnosed. Then there will be a scaling-up phase for patients, whilst simultaneously explaining health education for toothbrushing and dental floss training for all patients. The patients are then referred to the ward secretary who randomly selects and opens one of the 48 closed envelopes. This choice can be one of the pomegranate skin rinses, pomegranate seeds, saline or chlorhexidine 0.12%. Patients will be told to use mouthwashes or saline 2 times daily for 1 minute to 1 month, during which time they will not use any other medicines, pomegranates, or products containing pomegranate or other mouthwashes. After 2 weeks, 1 month and 3 months the patients will be recalled and the markers will be recorded by the same examiner who did not know the type of mouthwash.

##### Participants/Inclusion and exclusion criteria

In this study, 48 patients with severe chronic periodontitis were enrolled. Informed consent will be obtained from patients.

##### Intervention groups

Group A Physiological Serum (Control) Group B Pomegranate peel mouthwash Group pomegranate seed mouthwash Group D Chlorhexidine 0.12% Mouthwash

##### Main outcome variables

Depth of envelope SULCUS BLEEDING INDEX MODIFIED GINGIVAL INDEX

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200203046356N1**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

##### Registration date

2020-03-01, 1398/12/11

##### Registrant information

##### Name

fatemeh bazzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3341 3559

##### Email address

fatemeh.bazzi@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-04-18, 1399/01/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparative evaluation of the effect of pomegranate mouthrinse and chlorhexidine mouthrinse on severe chronic periodontitis treatment

**Public title**

The effect of pomegranate mouthwash

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients Referred to Zahedan Dental School No previous treatment of periodontitis No antibiotic use in the past 6 months Lack systemic diseases affecting the periodontium No corticosteroids use Non-pregnancy and lactation No smoking chronic severe periodontitis (clinical attachment loss more than 5 mm) measured by the Williams probe

**Exclusion criteria:**

If the patient consumes pomegranate or pomegranate products (such as pomegranate juice) or other mouthwash other than as prescribed during the study period, the patient will be excluded. unwillingness to participate in further study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The block randomization method is used and 48 closed envelopes are provided. People randomly select and open one. Of the 48 envelopes, 12 envelopes will be assigned to each of the A groups of placebo, B of pomegranate skin mouthwash, C of pomegranate seed mouthwash and D of chlorhexidine of 0.12%.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The envelopes containing the mouthwash codes are kept with the secretary and the mouthwashes containing physiological serum, pomegranate skin mouthwash and pomegranate seed mouthwash and chlorhexidine mouthwash are packed in similar containers and in groups (A) and (B) And (C) and (D) are named and coded. The codes for each container for the patient are unknown to the researcher and will be kept confidential until the end of the study by the supervisor.

**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. Hasabi Square, Zahedan University of Medical Sciences

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2020-01-26, 1398/11/06

**Ethics committee reference number**

IR.ZAUMS.REC.1398.382

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

Chronic periodontitis

**ICD-10 code**

K05.3

**ICD-10 code description**

Chronic periodontitis

**Primary outcomes****1****Description**

Depth of envelope

**Timepoint**

After 2 weeks, 1 month and 3 months of starting use of mouthwash

**Method of measurement**

By Williams Probe

**2****Description**

MODIFIED GINGIVAL INDEX

**Timepoint**

After 2 weeks, 1 month and 3 months of starting use of mouthwash

**Method of measurement**

By clinical examination

**3****Description**

SULCUS BLEEDING INDEX

#### Timepoint

After 2 weeks, 1 month and 3 months of starting use of mouthwash

#### Method of measurement

By clinical examination

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Control group: Physiological serum (placebo) is used twice a day for 1 minute to 1 month to wash the mouth.

##### Category

Placebo

#### 2

##### Description

Intervention group: Pomegranate peel mouthwash is used twice a day for 1 minute to 1 month to wash mouth.

##### Category

Treatment - Drugs

#### 3

##### Description

Intervention group: Pomegranate seed mouthwash is used twice a day for 1 minute to 1 month to wash the mouth.

##### Category

Treatment - Drugs

#### 4

##### Description

Intervention group: Chlorhexidine 0.12% mouthwash is used twice a day for 1 minute to 1 month to wash the mouth.

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Zahedan Dental School Priondontology section

###### Full name of responsible person

Fatemeh Bazzi

###### Street address

Eastern Azadegan Ave., Zahedan Dental School

###### City

Zahedan

###### Province

Sistan-va-Balouchestan

###### Postal code

9817699693

###### Phone

+98 54 3244 1814

###### Fax

+98 54 3241 4003

###### Email

fatemeh.bazzi@zaums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Zahedan University of Medical Sciences

###### Full name of responsible person

Fatemeh Bazzi

###### Street address

Azadegan Shargi St.

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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

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

Zahedan University of Medical Sciences

###### Full name of responsible person

Sanaz Isar

###### Position

B.Sc., Research Expert

###### Latest degree

Bachelor

###### Other areas of specialty/work

Library and Medical Information

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Azadegan Shargi St.

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Arbabi.Parvin@zaums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Parvin Arbabi Kalati

**Position**

Gum surgery Expert

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Bazzi

**Position**

دانشجو دندانپزشکی

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Email**

Fatemeh.bazzi@zaums.ac.ir

**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**

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

**Data Dictionary**

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