

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Investigating the effectiveness of mouthwash containing green tea extract and pomegranate peel, with and without zinc, compared to 0.12% chlorhexidine mouthwash on gingivitis in patients with gingivitis or mild chronic periodontitis: a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Comparing the effectiveness of mouthwash containing green tea extract and pomegranate peel, with and without zinc, compared to 0.12% chlorhexidine mouthwash on gingivitis.

##### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 105 patients. For random allocation, it is based on 6 random blocks, the sequence list of which will be determined through Random Allocation Software and will be placed in three groups.

##### Settings and conduct

The patients referred to the periodontology department of Gilan Faculty of Dentistry were asked to rinse twice a day (after brushing their teeth) for two weeks at the rate of 10 ml each time. After two weeks, the PBI (Papillary Bleeding Index), MGI (Modified Gingival Index), PI (Plaque Index) will be measured in patients. In this double-blind study, the researcher and researcher will be blinded. In this way, the mouthwashes were packed in the same size opaque white bottles so that the bottles are not distinguished from each other in terms of appearance. Data related to the type of mouthwash used by each group will not be provided to the statistician.

##### Participants/Inclusion and exclusion criteria

Entry criteria: 18 to 65 years old, having at least 20 natural teeth Exclusion criteria: patients with systemic diseases such as diabetes mellitus, pregnant and lactating women, smokers or tobacco users

##### Intervention groups

Group A and B will be the intervention, and the people of these groups will be given pomegranate peel extract-green tea-zinc mouthwash and pomegranate peel extract-green tea mouthwash respectively, and group C, which is the control group, will be given 0.12%

chlorhexidine. All patients are asked to rinse their mouth twice a day (after brushing) in the amount of 10 ml each time for two weeks.

##### Main outcome variables

PBI(papillary Bleeding Index) ,MGI(Modified Gingival Index) ,PI(Plaque Index)

#### General information

##### Reason for update

##### Acronym

CHX MW

##### IRCT registration information

IRCT registration number: **IRCT20221017056214N1**

Registration date: **2022-11-02, 1401/08/11**

Registration timing: **retrospective**

Last update: **2022-11-02, 1401/08/11**

Update count: **0**

##### Registration date

2022-11-02, 1401/08/11

##### Registrant information

##### Name

Bardia Vadiati

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3348 6422

##### Email address

dr.bardia\_vad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2022-08-01, 1401/05/10

**Expected recruitment end date**

2022-10-23, 1401/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effectiveness of mouthwash containing green tea extract and pomegranate peel, with and without zinc, compared to 0.12% chlorhexidine mouthwash on gingivitis in patients with gingivitis or mild chronic periodontitis: a double-blind randomized clinical trial

**Public title**

Investigating the effectiveness of mouthwash containing green tea extract and pomegranate peel, with and without zinc, compared to 0.12% chlorhexidine mouthwash on gingivitis in patients with gingivitis or mild chronic periodontitis: a double-blind randomized clinical trial

**Purpose**

Treatment

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

Having at least 20 natural teeth Suffering from gingivitis or mild chronic periodontitis Loss of clinical connections less than or equal to 2 mm Probe depth less than or equal to 3 mm will be included in the study

**Exclusion criteria:**

Allergic reaction to pomegranate Systemic diseases such as diabetes mellitus Pregnant and lactating women Cigarette or tobacco user Taking antibiotics or non-steroidal anti-inflammatory drugs in the 6 months before the study History of receiving periodontal interventions in the 6 months before the study

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**Target sample size: **105****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation was based on 6 random blocks, whose sequence list was determined by Random Allocation Software and placed in three groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Allocation concealment method was used in order to avoid the selection bias error (Information Bias). In this way, the number 1 to 35 was written on each envelope. In each envelope, based on the random numbers obtained, one of Three letters B, A and C were written and finally 35 envelopes were given to the second researcher. After the initial measurement of the indicators, the second researcher gave the corresponding mouthwash to the patients based on the number of patients written on the envelope and the intervention written inside the envelope. And they explained to the patients how to use it. In this study, researchers were blinded. In this way, the mouthwashes were packed in white opac bottles of the same size, so that the bottles cannot be distinguished from each other in terms of appearance. Only on the bottle of one of the three letters B, A and C, the pharmacist producing the mouthwashes was asked to write the content of each mouthwash in a closed letter and this letter should not be opened until the end of the study. Patients were not blinded in this study. For concealment, this list was kept in a sealed envelope in the research center or in the dental clinic office.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

So far, no study examines the synergistic effect of these two effective ingredients of green and pomegranate tea in control and improvement of periodontal diseases. Also, in previous studies, the effectiveness of zinc as a potent antioxidant has not been addressed to control the periodontal diseases, hence, we had an anti-inflammatory effect of mouthwash containing green tea extract and mouthwashes containing green tea extract\_ zinc in We compared the prevention and improvement of periodontal diseases.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gilan University of Medical Sciences

**Street address**

Sardar Soleimani's dormitory, Kargar alley 1, Lakan Blvd

**City**

Rasht

**Province**

Guilan

**Postal code**

4195735794

**Approval date**

2022-07-31, 1401/05/09

## Ethics committee reference number

1401.228

## Health conditions studied

### 1

#### Description of health condition studied

Mild chronic gingivitis or periodontitis

#### ICD-10 code

,K05.10

#### ICD-10 code description

Chronic gingivitis, plaque induced

## Primary outcomes

### 1

#### Description

Measuring the PBI index of the gingival groove is probed by using the Michigan O probe with Williams marking, in walking mode. 30 seconds after probing the gingival groove, the presence or absence of bleeding in 3 points on the buccal surface (mesiobuccal, midbuccal and distobuccal) and 3 points on the lingual surface (mesiolingual, midlingual and distolingual) will be checked and recorded. The number of bleeding areas will be calculated and this index will be reported as the percentage of bleeding dental surfaces compared to the total dental surfaces. MGI index of inflammation, color change and gum contour change will be checked in 6 points around all teeth. 3 points on the buccal level (mesiobuccal, midbuccal and distobuccal) and 3 points on the lingual level (mesiolingual, midlingual and distolingual) are evaluated and each one will be given a score from 0 to 4. So that score 0 is without inflammation; score 1, the presence of mild inflammation with a slight change in color and contour in parts of the gum; score 2, the presence of mild inflammation in the entire gum; Score 3 means moderate inflammation and score 4 means severe inflammation. The average of the obtained numbers will be calculated and reported. To measure the PI index, patients are asked to chew Fushin tablets for 60 seconds and then rinse their mouths. Stained surfaces will be considered as positive surfaces. Unpainted surfaces are considered as negative surfaces. Staining or not staining will be evaluated at 4 points including midbuccal, mesial papillae, midlingual and distal papillae. This index is reported as the percentage of stained areas compared to the total tooth surfaces.

#### Timepoint

Indicators are measured 2 weeks after using the mouthwash.

#### Method of measurement

MGI index and PI index are clinically evaluated based on the indices. 30 After exploring the gingival groove, the presence or absence of presence is checked.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: patients in a questionnaire based on the block sequence list, in one of groups A (mouthwash containing pomegranate peel extract and green tea, with zinc), B (mouthwash containing pomegranate peel extract and green tea, without zinc) and C (chlorhexidine mouthwash 0.12%) and received the corresponding mouthwash. Group A was the intervention; The people of this group were given green tea extract - pomegranate peel - zinc mouthwash. Group B was the same as the second intervention group, this group was given green tea extract-pomegranate skin mouthwash.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: group C (the third group), which is the control group, was given 0.12% chlorhexidine. All patients were asked to use the given mouthwash (green tea extract-pomegranate peel-zinc mouthwash for group A, green tea extract extract-pomegranate peel mouthwash for group B and chlorhexidine 0.12% for group C) twice a day for two weeks. (after brushing teeth) use 10 ml of mouthwash each time. and if using mouthwash, record and report its consumption as follows.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Academic Complex of Gilan University of Medical Sciences, Department of Periodontology

##### Full name of responsible person

Mobina ghorbani

##### Street address

Academic Complex of Gilan University of Medical Sciences, Department of Periodontology, In front of Khazar and Padideh restaurants, 2 km to Fuman, Saravan belt, The end of the Lacan road, gas field

##### City

Rasht

##### Province

Guilan

##### Postal code

4194173774

##### Phone

+98 13 3348 6406

##### Fax

+98 13 3348 6423

**Email**

Ghorbani.mobinaa@gmail.com

**Web page address**

<http://dental.gums.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

bardia vadiati

**Street address**

Academic Complex of Gilan University of Medical Sciences, Department of Periodontology, In front of Khazar and Padideh restaurants, 2 km to Fuman, Saravan belt, The end of the Lacan road, gas field

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**Email**

Dr.bardia\_vad@yahoo.com

**Web page address**

<https://dental.gums.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Paid in person.

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Bardia vadiati

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Periodontologist

**Street address**

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0981333486406

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**Web page address**

[https://dental.gums.ac.ir](https://dental.gums.ac.ir/)

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Bardia vadiati

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Bardia vadiati

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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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**

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