Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,Lacan 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
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Email
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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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Phone
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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
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City
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Province
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Postal code
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Phone
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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
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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Web page address
https://dental.gums.ac.ir

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

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

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Dr.bardia_vad@yahoo.com

Web page address

https://dental.gums.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