Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation the effect of mouth wash contains punica granatum extract in comparison with chlorhexidine mouth wash on improvement of periodontal index in chronic mild to moderate periodontitis

Protocol summary

Study aim
Evaluation the effect of mouth wash contains punica granatum extract in comparison with chlorhexidine mouth wash on improvement of periodontal index in mild to moderate chronic periodontitis.

Design
non randomized double blind clinical trial with control group, parallel groups, third phase on 30 patients.

Settings and conduct
It will be performed at the periodontolgy department of Alborz Dental University.executor, clinical caregiver, data analyzer, outcome assessor, the person under study and data analyzer are blinded. people with all the inclusion criteria are selected and then all the required information is provided to them and if they are satisfied date of first session will be fixed.

Participants/Inclusion and exclusion criteria
"inclusion criteria":not smoker؛ not alcohol consumer؛ no antibiotic intake؛ not pregnant؛ no history of allergic reaction؛ no systematic disease؛ not in breast feeding period؛ has mild to moderate chronic periodontitis. they should have mild to moderate periodontitis.

Intervention groups
"Intervention group:" Ultrasonic scaling is performed as the first line of treatment for patients with mild to moderate periodontitis. The patient will use mouthwash for two weeks that containing 2% punica granatum extract which produced in the Faculty of Pharmacy of Alborz University of Medical Sciences twice a day and 1 minute each time. 1 month and 3 months after scaling, he refers to check and re-measure gingival indices. "Control group:" completely identical to the intervention group, only mouthwash is replaced with 0.2% chlorhexidine from NAJO company.

Main outcome variables
gingival index, pocket depth, bleeding on probing, clinical attachement loss, bacterial culture

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210404050830N1**
Registration date: **2021-11-12, 1400/08/21**
Registration timing: **retrospective**

Last update: **2021-11-12, 1400/08/21**
Update count: **0**

Registration date
2021-11-12, 1400/08/21

Registrant information

Name
Ali Bayat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4465 4507

Email address
alibt77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-07-11, 1400/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of mouth wash contains punica granatum extract in comparison with chlorhexidine mouth wash on improvement of periodontal index in chronic mild to moderate periodontitis

Public title
effect of maouthwash contains punica granatum extract on periodontitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
not alcohol consumer non smoker not pregnant no antibiotic usage no allergic reaction not breastfeeding no systematic disease mild to moderate chronic periodontitis
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the block randomization method. This method is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and in this two-group experiment, we will have 4 blocks of 8 (including 4 people participating in the intervention group and 4 people participating in the control group), Due to the possibility of people not attending the follow-up sessions, 2 people are considered more than the sample size. The site https://www.sealedenvelope.com/simple has been used for random assignment of individuals to groups. In this method we use sealed envelopes with a random sequence. Each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes open in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The codes for each group will be kept in a closed envelope. After the person is eligible to enter the study, based on the obtained sequence, one of the two interventions will be performed for him. The solutions are in the same jars and are similar in color and size, and no one untill the end of the study, when the research report is being prepared, neither the researcher, nor the assistant, nor the participant has any knowledge that labels A or B belong to the intervention or control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Katooei st, Golshahr, Karaj
City
Karaj
Province
Alborz
Postal code
3198684868

Approval date
2021-01-19, 1399/10/30

Ethics committee reference number
IR.ABZUMS.REC.1399.256

Health conditions studied

1

Description of health condition studied
Chronic mild to moderate periodontitis.

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
periodontal pocket depth

Timepoint
before intervention, after 1 month, after 3 month

Method of measurement
with WHO periodontal probe

2

Description
clinical attachement loss
Timepoint
before intervention, after 1 month, after 3 month
Method of measurement
with WHO periodontal probe

3

Description
gingival index
Timepoint
before intervention, after 1 month, after 3 month
Method of measurement
with WHO periodontal probe

4

Description
bleeding on probing
Timepoint
before intervention, after 1 month, after 3 month
Method of measurement
with WHO periodontal probe

5

Description
bacterial culture
Timepoint
before intervention, after 1 month, after 3 month
Method of measurement
pharmacoupe culture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Before any intervention,The patient will be taught how to brush and floss properly and how to use mouthwash properly for 15 minutes.Then all the variables, including the depth of the periodontal pocket and gingival index and clinical attachment loss and bleeding during probing(by WHO periodontal probe) and bacterial culture are recorded in the patient's file at the first meeting before any intervention. Then scaling is done by ultrasonic scaler for the patient. up to two weeks after scaling the patient uses mouthwash containing 2 percent punica granatum extract that produced by Pharmacy Faculty of Alborz University of Medical Sciencestwice a day. 1 month later and 3 months after scaling, the patient is called to re-examine the gingival markers. Then the results are compared with the results of control group.
Category
Treatment - Other

2

Description
control group: Before any intervention,The patient will be taught how to brush and floss properly and how to use mouthwash properly for 15 minutes.Then all the variables, including the depth of the periodontal pocket and gingival index and the amount ofclinical attachment loss and bleeding during probing(by WHO periodontal probe) and bacterial culture are recorded in the patient's file at the first meeting before any intervention. Then scaling is done by ultrasonic scaler for the patient. up to two weeks after scaling the patient uses mouthwash containing 0.2 percent chlorhexidine(NAJO) twice a day. 1 month later and 3 months after scaling, the patient is called to re-examine the gingival markers.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry faculty of Alborz University of Medical Sciences
Full name of responsible person
Ali Bayat
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Katooei st, Golshahr, Karaj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Doctor hatam godini
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Fax

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Email

h.godini@abzums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Ali Bayat

Position

Dental intern

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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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