

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 periodontology 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 diseases! 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 attachment 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 until 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 attachment 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 Science twice 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 of 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 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

Street address

Katooei st, Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198684868

Phone

+98 26 3355 5110

Email

alibt77@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Doctor hatam godini

Street address

Safarian st, Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 4083

Fax

+98 26 3464 3705

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

Street address

Number20, West 5th, Tohid ave,Tehranpars, Tehran

City

Tehran

Province

Tehran

Postal code

1653636411

Phone

+98 21 4465 4507

Email

alibt77@gmail.com

Person responsible for scientific 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

Street address

Number 20, west 5th, street Tohid ave., Tehranpars, Tehran

City

Tehran

Province

Tehran

Postal code

1653636411

Phone

+98 21 4465 4507

Email

alibt77@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Ali bayat

Position

Dental intern

Latest degree

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Other areas of specialty/work

Dentistry

Street address

Number 20, 5th west street, Tohid ave., Tehran pars, Tehran

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Tehran

Province

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Phone

+98 21 4465 4507

Email

alibt77@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

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

