

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

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Eastern Azadegan Ave., Zahedan Dental School

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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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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