

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare the Effect of chlorhexidine with Terminalia chebula mouthwash as Adjunctive Therapy in Patients with Chronic Periodontitis

Protocol summary

Study aim

This study was performed to compare the effect of two types of mouthwash on the clinical improvement of chronic periodontitis.

Design

Clinical trial, double-blind, randomized, on 36 patients

Settings and conduct

36 patients with mild to moderate periodontitis were selected based on inclusion and exclusion criteria in the periodontal department of Islamic Azad University of Isfahan Dental School. The selected patients in the age group of 35-65 years had at least 20 teeth and plaque index below 40%. After the first phase of periodontal treatment including scaling and root planing, the patients were divided into two groups (first group: 0.2% chlorhexidine, second group: Terminalia chebula mouthwash). The mouthwashes were given to the patients in uniform dishes to use twice a day for two weeks, each 10 ml for 1 minute and 30 minutes after brushing. Periodontal indices were recorded and compared on days 1 and 15. Data were analyzed using Shapiro-wilk test, independent t-test and SPSS software version 22.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) patients with mild to moderate chronic periodontitis 2) Patients in the age range of 35-65 years have at least 20 teeth and have a plaque index below 40% Exclusion Criteria: 1) Patients with orthodontic plaque or fixed and movable Parsil prosthesis 2) patients with any systemic disease 3) pregnant and lactating women 4) Antibiotic therapy in past 3 months 5) People with chlorhexidine mouthwash allergies 6) Scalling or gingival surgery in past 6 months

Intervention groups

Group A: chlorhexidine mouthwash Group B: Terminalia chebula mouthwash

Main outcome variables

Plaque index , pocket depth, Clinical attachment level, Bleeding on Probing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200517047486N1**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **retrospective**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Mina Rezvani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-27, 1398/04/06

Expected recruitment end date

2019-10-28, 1398/08/06

Actual recruitment start date

2019-07-28, 1398/05/06

Actual recruitment end date

2019-10-28, 1398/08/06

Trial completion date

2019-10-28, 1398/08/06

Scientific title

Compare the Effect of chlorhexidine with Terminalia chebula mouthwash as Adjunctive Therapy in Patients with Chronic Periodontitis

Public title

Comparison of the effect of chlorhexidine and Terminalia chebula mouthwash in chronic periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with mild to moderate chronic periodontitis
Patients in the age range of 35-65 years have at least 20 teeth and have a plaque index below 40%

Exclusion criteria:

Patients with orthodontic plaque or fixed and movable Parsil prosthesis patients with any systemic disease
pregnant and lactating women Antibiotic therapy in past 3 months People with chlorhexidine mouthwash allergies
Scaling or gingival surgery in past 6 months

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

We used the law of random allocation. First, we prepared an equal number of 18 balls in two colors, white and red, in the size of a sample size of 36, and then placed them in a lottery container. 18 red balls belonged to the chlorhexidine group and 18 white balls belonged to the terminalia chebula group. We placed all the balls in the lottery container and then randomly removed the balls from the container without replacement and recorded the created sequence and assigned this recorded sequence to the list number of individuals and thus the two groups to Were randomly selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Mouthwashes are given to patients in the same container and shape, and after two weeks that the patients were treated with mouthwash, they are examined again by clinicians who do not know their grouping in the same conditions, and all the studied indicators are registered for them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research Ethics Committee Islamic Azad University - Isfahan (Khorasgan) Branch

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university Blvd- Arqavanieh, Jey Street

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Approval date

2019-09-03, 1398/06/12

Ethics committee reference number

IR.IAU.KHUISF.REC.1398.179

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

Plaque index

Timepoint

The first and fifteenth days of study

Method of measurement

Sillness and Loe

2

Description

pocket depth

Timepoint

The first and fifteenth days of study

Method of measurement

peridontal probe

3

Description

Clinical attachment level

Timepoint

The first and fifteenth days of study

Method of measurement

peridontal probe

4**Description**

Bleeding on Probing

Timepoint

The first and fifteenth days of study

Method of measurement

peridontal probe

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Use chlorhexidine mouthwash(0.2%); Patients, turn chlorhexidine mouthwash(Vi- one, Tabriz, Iran) in their and take it out mouth for 2 weeks, twice a day(morning and night) each time 10 ml for 1 minute, 30 minutes after brushing. Periodontal Parameters are recorded on days (1) and (15).

Category

Treatment - Drugs

2**Description**

Intervention group: Use Terminalia chebula moutwash. Patients, turn Terminalia chebula moutwash in their and take it out mouth for 2 weeks, twice a day(morning and night) each time 10 ml for 1 minute, 30 minutes after brushing. Periodontal Parameters are recorded on days (1) and (15).Terminalia chebula mouthwash is prepared by boiling 10 grams of Triphala powder into 10 ml of boiling water.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Islamic Azad University of Isfahan (Khorasgan)

Full name of responsible person

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

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

mina rezvani

Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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