Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 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 Shapirovilk 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)

Phone

+98 31 3500 2134

Email address

mina.rezvani@khuisf.ac.ir

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 Scalling 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 terminala 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

Street address
university Blvd- Arqavanieh, Jey Street

City
Esfahan

Province
Isfehan

Postal code
۸۱۵۵۱-۳۹۹۹۸

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 cholorhexidine 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
Mina Rezvani
Street address
university Blvd- Arqavanieh, Jey Street
City
Esfahan
Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Phone
+98 31 3500 2141
Email
mina.rezvani@khuisf.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
majid toghiani
Street address
university Blvd- Arqavanieh, Jey Street
City
Esfahan
Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Phone
+98 31 3500 2552
Email
toghiani@hotmail.com
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
Street address
university Blvd- Arqavanieh, Jey Street
City
Esfahan

Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Phone
+98 31 3500 2141
Email
mina.rezvani@khuisf.ac.ir

Person responsible for scientific 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
Street address
university Blvd- Arqavanieh, Jey Street
City
Esfahan
Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Phone
+98 31 3500 2141
Email
mina.rezvani@khuisf.ac.ir

Person responsible for updating data

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
Street address
university Blvd- Arqavanieh, Jey Street
City
Esfahan
Province
Isfehan
Postal code
۸۱۵۵۱-۳۹۹۹۸
Phone
+98 31 3500 2141
Email
mina.rezvani@khuisf.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