Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Effectiveness of Propolis and Chlorhexidine Mouthwash on Gingival Inflammation in Chronic Gingivitis

Protocol summary

Study aim
Determination of the effect of mouthwash containing Propolis on plaque, gingival and periodontal indices in patients with chronic gingivitis

Design
According to the random numbers table, patients who are eligible for inclusion in the study are randomly divided into two groups of 20. All types of mouthwashes are placed in the same glass and encoded in such a way that the patient and the host of the design will not be aware of it.

Settings and conduct
The place of study is at Mashhad University of Medical Science. Two groups of 20 who took Group 1 Propolis mouthwash and Group 2 Chlorhexidine mouthwash, and plaque, gingival and periodontal indices were administered on that time, two weeks later, three weeks later and four weeks later. The results will be recorded by someone else based on the given codes and will be Blind. Study is Clinical trial Double-Blinded how the Investigator, participant and outcome assessor are Blind, and is described to patients who receive one of the Chlorhexidine or Propolis mouthwashes.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Have Public Health No Need Prophylaxis Not Using Anti Inflammation Within Six Weeks and at the Time of Review Not Using Drugs like Antihistamine, antidepressant or Analgesic Within Six Weeks and at the Time of Review No Attachment Loss Not Pregnant Exclusion criteria : Pregnancy or Breastfeeding Tobacco use Systemic disease Unwillingness or patient cooperation Receive antibiotics over the past 2 weeks History of using mouthwash in a recent month Patients with a history of allergy to honey and wax compounds

Intervention groups
Propolis and Chlorhexidine mouthwash

Main outcome variables
Gingival index(GI) , plaque index (PI) and Periodontal index (CPI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180528039880N1**
Registration date: **2018-07-05, 1397/04/14**
Registration timing: **prospective**

Last update: **2018-07-05, 1397/04/14**
Update count: **0**

Registration date
2018-07-05, 1397/04/14

Registrant information

Name
Amirali Fazeli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3502 9626

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fazeliaa911@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-05-22, 1398/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Propolis and Chlorhexidine Mouthwash on Gingival Inflammation in Chronic Gingivitis

Public title
Comparison of the Effectiveness of Propolis and Chlorhexidine Mouthwash on Gingival Inflammation in Chronic Gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have Public Health No Need Prophylaxis Not Using Anti Inflammation Within Six Weeks and at the Time of Review Not Using Drugs like Antihistamine, antidepressant or Analgesic Within Six Weeks and at the Time of Review No Attachment Loss Not Pregnant

Exclusion criteria:
Pregnancy or Breastfeeding Tobacco use Systemic disease Unwillingness or patient cooperation Receive antibiotics over the past 2 weeks History of using mouthwash in a recent month Patients with a history of allergy to honey and wax compounds

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
More than 1 sample in each individual
Number of samples in each individual: **20**
receiver of Propolis Mouthwash and Chlorhexidine Mouthwash

Randomization (investigator's opinion)
Randomized

Randomization description
table of random numbers. All types of mouthwashes are placed in the same glass and encoded in such a way that the patient and the host of the design will not be aware of it. The results will be recorded by someone else based on the given codes and will be Blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
All types of mouthwashes are placed in the same glass and encoded in such a way that the patient and the host of the design will not be aware of it. The results will be recorded by someone else based on the given codes and will be Blind. Study is Double-Blinded how the Investigator, participant and outcome assessor are Blind, and is described to patients who receive one of the Chlorhexidine or Propolis mouthwashes

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Park Square, Vakilabad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Approval date
2018-06-21, 1397/03/31

Ethics committee reference number
IR.mums.sd.REC.1394.244

Health conditions studied

1

Description of health condition studied
Chronic Gingivitis

ICD-10 code
K05.1

ICD-10 code description
Chronic gingivitis

Primary outcomes

1

Description
Gingival index (GI) and Plaque index (PI) and Community Periodontal index (CPI)

Timepoint
At the beginning of the study (before the intervention), two weeks, three weeks and four weeks after the intervention began

Method of measurement
universal probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Propolis mouthwash. The chemical composition of Propolis is very complex, depending on the species of bee, the type of plant origin and the climate of the corresponding geographical area. Propolis contains wax (most of it), gum and resin, pollen and active ingredients (minerals and vitamins). The Participant is asked to use mouthwash twice a day after the toothbrush for ten days. The patient should hold 15 cc mouthwashes every time for a minute and then abstain from eating and drinking for 30 minutes and not using another mouthwash during the study period.

Category
Treatment - Drugs

2

Description
Control group: chlorhexidine mouthwash 0.12% The Participant is asked to use mouthwash twice a day after the toothbrush for ten days. The patient should hold 15 cc mouthwashes every time for a minute and then abstain from eating and drinking for 30 minutes and not using another mouthwash during the study period.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad University of Medical Science

Full name of responsible person
Amirali Fazeli

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Park square, Vakilabad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majidreza Mokhtari

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Amirali Fazeli

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amirali Fazeli
Position
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Latest degree
A Level or less
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
available for people working in academic institutions and people working in businesses
Under which criteria data/document could be used
Not required more terms
From where data/document is obtainable
Amirali Fazeli Phone number 00989336957522 e-mial : fazeliaa911@mums.ac.ir
What processes are involved for a request to access data/document
documents /data files are recieved within one week
Comments