

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)

Phone

+98 51 3502 9626

Email address

fazeliala911@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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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
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Full name of responsible person
Amirali Fazeli
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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