

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of the effectiveness of mucoadhesive mouthwash containing propolis extract formulation on prevention and improvement of symptoms in patients with generalized chronic gingivitis

Protocol summary

Study aim

Determining the effect of propolis mouthwash on generalized chronic gingivitis

Design

Randomized clinical trial with two control groups, with parallel groups, double-blind, phase 2 on 78 patients using www.randomization.com for randomization.

Settings and conduct

We have three groups of 26 patients. For each patient, scaling is done first, then mouthwash is given, and we ask the patient to use mouthwash twice a day (10 cc/turn) for 14 days. Indicators are measured twice, once before scaling and once at the end of day 14. Blinding is performed for the patient and the person examining the outcome. The study platform is Mashhad Dental School.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient does not have a systemic problem, Patient has generalized chronic gingivitis, Patient has filled out an informed consent form, Patient has no history of smoking Exclusion criteria: Pregnant patients, Patients who are unable to attend in follow up sessions, Patients receiving antibiotics systemically or topically, Breastfeeding patients, Using anti-inflammatory medications during the study, Using anti-coagulant medications during the study, Using immune-suppressive medications during the study, Patients receiving orthodontic therapy

Intervention groups

We have three groups, one group will receive mucoadhesive mouthwash of propolis (5%), and two control groups including placebo and chlorhexidine. We will ask the patient to use mouthwash twice a day (10 cc/turn) for 14 days

Main outcome variables

Examination of plaque indices, BOP, gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038558N1**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **prospective**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Naser Sargolzaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3602 5063

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of mucoadhesive mouthwash containing propolis extract formulation on prevention and improvement of symptoms in patients with generalized chronic gingivitis

Public title

Effect of propolis on generalized chronic gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient does not have a systemic problem Patient has generalized chronic gingivitis Patient has filled out an informed consent form Patient has no history of smoking

Exclusion criteria:

Pregnant patients Patients who are unable to attend in follow up sessions Patients receiving antibiotics systemically or topically Breastfeeding patients Using anti-inflammatory medications during the study Using anti-coagulant medications during the study Using immune-suppressive medications during the study Patients receiving orthodontic therapy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method, the size of blocks is equal to six with three members A and B and C in a ratio of 1: 1:1. Based on the sample size, 13 blocks are numbered in a different order from 1 to 13 and a random sequence of 13 blocks is determined using the site " <http://www.randomization.com>", then the sequence of treatment groups A and B and C is determined in envelopes with number 1 Up to 78, with the inclusion of each eligible person, the envelope corresponding to the person's number is opened and the treatment group is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the use of a placebo similar to the intervention treatment, the physician associated with the participants and participants will not be informed of the assigned treatment. Also, the analyst will be unaware of the treatment assigned to the three groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B and C. The placebo will be very similar in treatment in terms of shape,

consistency, packaging, and smell.

Placebo

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 Science

Street address

Vakil Abad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-10-22, 1400/07/30

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1400.104

Health conditions studied

1

Description of health condition studied

Generalized Chronic Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

Examination of plaque indices

Timepoint

At the beginning of the study (before the start of the SRP) and 14 days later

Method of measurement

observation and check list of Turesky modification of the Quigley-Hein Plaque (MQH) Index

2

Description

Bleeding on probing (BoP)

Timepoint

At the beginning of the study (before the start of the

SRP) and 14 days later

Method of measurement

observation and check list of Gingival bleeding index (GBI)

3

Description

Examination of gingival index

Timepoint

At the beginning of the study (before the start of the SRP) and 14 days later

Method of measurement

observation and check list of Modified Gingival Index (MGI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: mucoadhesive mouthwash with 5% propolis that every patient should use and rinse mouthwash for 30 seconds twice a day for 14 days and avoid eating and drinking for 30 minutes after use.

Category

Treatment - Drugs

2

Description

Control group: Chlorhexidin mouthwash that every patient should use and rinse mouthwash for 30 seconds twice a day for 14 days and avoid eating and drinking for 30 minutes after use.

Category

Treatment - Drugs

3

Description

Control group: Placebo mouthwash containing the base of propolis mouthwash that is the same as coloring, tasting, smelling and appearance. Every patient should use and rinse mouthwash for 30 seconds twice a day for 14 days and avoid eating and drinking for 30 minutes after use.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Dr. Nasser Sargolzaei

Street address

Vakil abad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarehan

Street address

University Street - next to Hoveyzeh Cinema - Ghorashi Building - Deputy of Research and Technology

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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

Dr. Nasser Sargolzaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Periodontics

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At the beginning of Vakilabad Boulevard, in front of Mellat Park - School of Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Naser Sargolzaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

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