

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparative study of periodontal clinical indexes after oral administration with Propolis and placebo in patients with gingivitis

Protocol summary

Study aim

Clinical evaluation of Propolis mouthwash efficacy in gingival inflammatory disease

Design

Randomized controlled clinical trial, parallel group, triple blinded, phase 2-3 on 30 participants, randomization with random number table

Settings and conduct

Place: Specialized department of the Faculty of Dentistry, University of Isfahan. Conduct: Selection of 30 patients by easy sampling method. Method: Randomized allocation of patients into case and control groups. Blinding: Everyone is blinded because Propolis and placebo mouthwashes have A and B labels.

Participants/Inclusion and exclusion criteria

Eighteen- fifty years patients with gingivitis , having a minimum of 20 teeth, and absence of dental calculus who are systemically healthy. The smokers, pregnant patients, the patients who intake anti-inflammatory or antibiotic medications in the past 1 month and patients with orthodontic appliances will not enter study.

Intervention groups

The intervention group will receive a mouthwash containing propolis while the control group will receive the placebo mouthwash. The patients will be instructed oral hygiene equally and will use the mouthwash in 15 days according to the manufacturer's instructions.

Main outcome variables

To benefit anti-inflammatory and anti-bacterial benefits of Propolis extract in decreasing gingival bleeding and inflammation and bacterial plaque.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021029N3**

Registration date: **2020-08-11, 1399/05/21**

Registration timing: **retrospective**

Last update: **2020-08-11, 1399/05/21**

Update count: **0**

Registration date

2020-08-11, 1399/05/21

Registrant information

Name

Sima Kiani

Name of organization / entity

Department of Periodontology, dental school, Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-01, 1399/03/12

Expected recruitment end date

2020-08-02, 1399/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of periodontal clinical indexes after oral administration with Propolis and placebo in patients with gingivitis

Public title

Propolis mouthwash effect on gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 and under 50 years Systemically healthy
Having gingivitis Absence of dental calculus Having a minimum of 20 teeth Acceptable cooperation Sign the consent form

Exclusion criteria:

smoking pregnancy intake of anti-inflammatory or antibiotic medications in the past 1 month presence of systemic diseases orthodontic treatment with fixed or removable appliances scaling in the past 1 month

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants selection in the study will perform by simple randomization method, individually and with random number table tools. In this way, a number will be written in front of the name of each person from the list of clients, then a table will be designed based on the sample size of the study, and we'll blindly touch a number of table numbers. The selected numbers will be included in the study if they are eligible after the examination. The intervention will be performed in a parallel design, and the choice of individuals for Intervention or Control will be randomly performed with coin instruments. In such a way that for both people whose names are accidentally put in the list, the first person uses mouthwash A and the second B uses heads, and vice versa if it is tails.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants: the individuals will receive unnamed mouthwash bottles with labels A and B. care provider: This person will give the mouthwash bottles to the participants randomly, Then he/she will register their names in list A or B, while he/she is unaware about the bottles content. investigator: investigator will be unaware about patients category during indices evaluation until end of study. Outcome assessor: its the same investigator.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical sciences, Hezarjerib Ave, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-06-20, 1396/03/30

Ethics committee reference number

IR.MUI.REC.1396.3.947

Health conditions studied

1

Description of health condition studied

Plaque induced chronic gingivitis

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes

1

Description

Papillary Bleeding Index (PBI)

Timepoint

At baseline (before the intervention) and at 15 and 30 days, after mouthwash application

Method of measurement

By periodontal probe and visual evaluation

2

Description

Plaque Index (PI)

Timepoint

At baseline (before the intervention) and at 15 and 30 days, after mouthwash application

Method of measurement

By periodontal probe and visual evaluation

Secondary outcomes

1

Description

Stain index

Timepoint

At baseline (before the intervention) and at 15 and 30 days, after mouthwash application

Method of measurement

Visual evaluation

Intervention groups

1

Description

Intervention group: In this group the mouthwash contained Propolis extract will be prescribed. The application instructions for mouthwash will be described to patients according to the manufacturer's instructions: 30 drops of the mouthwash must be dissolved in 20 mL of water and used twice a day each time for 1 to 15 minutes for 4 weeks

Category

Treatment - Other

2

Description

Control group: placebo mouthwash application. The application instructions for mouthwash will be described to patients according to the manufacturer's instructions: 30 drops of the mouthwash must be dissolved in 20 ml of water and used twice a day each time for 1 to 15 minutes for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences, School of Dentistry

Full name of responsible person

Sima Kiani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sima Kiani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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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

Not applicable

Title and more details about the data/document

Data related to Personal information and Indicators examined in the study. All Data can be shared after People have not been identified

When the data will become available and for how long

Up to One year after publication of the Article

To whom data/document is available

Researchers working in Academic and Scientific Institutions

Under which criteria data/document could be used

In addition to mentioning the Name and Academic affiliation, the Applicant must have signed a letter stating that He or She does not intend to publish or use any of our study Data in Person

From where data/document is obtainable

Applicants can contact this E-mail: skiani.dnt@gmail.com

What processes are involved for a request to access data/document

The Project Manager will provide the requested Documents via E-mail no later than One week after receiving the E-mail from the Applicant

Comments