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
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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

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Province

Isfehan

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
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Sponsors / Funding sources

1

Sponsor
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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
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Latest degree
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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