Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing The Effect of Propolis Extract and Chlorhexidine Mouthwash on Clinical Parameters and Salivary Level of Matrix Metalloproteinase 8 in Chronic Periodontitis Patients: A Randomized Controlled Clinical Trial

Protocol summary

Summary

This study aimed to compare the efficacy of Propolis Extract and Chlorhexidine Mouthwash in chronic periodontitis patients. This phase 3 RCT will be conducted on 24 patients presented to Tehran University of Medical Sciences, School of Dentistry, International Campus, in the age range of 25 to 50 years with deep pockets (≥5 mm) around a minimum of three teeth.The exclusion criteria are presence of periapical changes in the respective teeth, systemic conditions requiring antibiotic prophylaxis or affecting the progression of disease or response to treatment. The patients will be randomly divided into two groups of propolis and chlorhexidine. Patients in chlorhexidine group undergo SRP and using 0.2 % chlorhexidine mouthwash twice a day for two weeks. In the propolis group, SRP will be performed followed by irrigation with 3 cc of hydroalcoholic solution of propolis extract twice a week for two weeks. Clinical parameters including gingival index (GI), bleeding on probing (BOP), pocket probing depth (PPD) and clinical attachment level (CAL) will be measured at baseline (onset of treatment) and one month after treatment. Saliva samples will be collected at baseline and one month later to evaluate the salivary level of Matrix Metalloproteinase 8 using ELISA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122030475N3**
Registration date: **2017-02-02, 1395/11/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-02, 1395/11/14

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Vice Chancellor for research of International Campus, Tehran University of Medical Sciences

Expected recruitment start date
2017-01-20, 1395/11/01

Expected recruitment end date
2017-05-19, 1396/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing The Effect of Propolis Extract and Chlorhexidine Mouthwash on Clinical Parameters and Salivary Level of Matrix Metalloproteinase 8 in Chronic Periodontitis Patients: A Randomized Controlled Clinical Trial

Public title

Effect of Propolis Extract on Chronic Periodontitis Patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Chronic periodontitis patients; The age range of 25 to 50 years; Having deep periodontal pockets (≥5 mm) around a minimum of three teeth not adjacent to each other. Exclusion criteria: Presence of periapical changes in the respective teeth; Systemic conditions requiring antibiotic prophylaxis or affecting the progression of disease or response to treatment; History of periodontal therapy in the past six months; Use of antibiotics, Anti-inflammatory drugs, anticonvulsants, immunosuppressive drugs or calcium channel blockers in the past three months; Pregnancy; Orthodontic treatment; Smoking; Having pacemaker; Mitral valve prolapse, Use of mouthrinses during treatment.
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
For the purpose of randomization, in every 10 patients, 10 envelops will be allocated; out of which, five containing propolis extract and the remaining five containing chlorhexidine mouthwash. By doing this, patients will be randomly divided into test propolis and chlorhexidine groups. After completion of randomization of the first 10 patients, this procedure will be repeated.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of International Campus, Tehran University of Medical Sciences
Street address
Mahan street, Zamzam street, khaniabade no, Navvab highway, Tehran.
City
Tehran
Postal code
Approval date
2015-11-02, 1394/08/11
Ethics committee reference number
IR.TUMS.REC.1394.1066

Health conditions studied

1

Description of health condition studied
Chronic periodontits
ICD-10 code
K05.3
ICD-10 code description
chronic pericoronitis Periodontitis: NOS complex simplex

Primary outcomes

1

Description
Clinical Attachment level (CAL)
Timepoint
Before intervention and one month later
Method of measurement
mm using periodontal probe

2

Description
Pocket Depth (PD)
Timepoint
Before intervention and one month later
Method of measurement
mm using periodontal probe

3

Description
Bleeding on probing (BOP)
Timepoint
Before intervention and one month later
Method of measurement
positive or negative, using periodontal probe

4

Description
Gingival index (GI)
Timepoint
Before intervention and one month later
Method of measurement
Average number of teeth with positive bleeding on probing, using periodontal probe

5

Description
Matrix Metalloproteinase 8 level of saliva
Timepoint

Before intervention and one month later

Method of measurement

Pg/ml, ELISA TEST

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, after SRP, the respective areas will be irrigated with 3cc of hydro-alcoholic solution of propolis extract 20 % (Soren Tech, Mashhad, Iran) twice a week for two weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, after SRP, 0.2 % chlorehexidine mouthwash (Shahredaru, Tehran, Iran) is prescribed for use twice a day for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, International Campus, Tehran University of Medical Sciences.

Full name of responsible person

Street address

Mahan street, Zamzam street, khaniabade no, Navvab highway, Tehran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of International Campus, Tehran University of Medical Sienses.

Full name of responsible person

Mitra Montazerlotf

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Mahan street, Zamzam street, khaniabade no, Navvab highway, Tehran.

City

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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

Vice chancellor for research of International Campus, Tehran University of Medical Sienses.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Dentistry, International Campus, Tehran University of Medical Sciences.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty