

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of toothpaste with propolis in Prevention of microbial Plaque formation

Protocol summary

Summary

Aim: To compare the clinical effect of propolis toothpaste and regular toothpaste to prevent dental plaque formation. The study was double blind and crossover trial on 40 students carried out. Inclusion criterion: all persons have teeth and without periodontal disease. Exclusion criteria: individuals who have: orthodontic brackets and band; partial dentures; more than three crown in the mouth and 4 or more than 4 millimeter pocket in 4 quadrant. Twenty of case as first group brush with propolis toothpaste for 2 weeks and the same control as second group brush with traditional toothpaste (without propolis).after recording of plaque index ,The two groups don't do plaque control for 48 hours.Then ,The second group as case group brush with propolis toothpaste and first group as control use traditional toothpaste for 2 weeks.(crossover method). The primary outcome of the study is microbial plaque that with the method of öleary plaque index is recorded at baseline and 2 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060313576N1**

Registration date: **2013-07-17, 1392/04/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-17, 1392/04/26

Registrant information

Name

Majid Fereidooni

Name of organization / entity

Faculty of Dentistry, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Babol Faculty of Dentistry-babol medical science

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of toothpaste with propolis in Prevention of microbial Plaque formation

Public title

The effect of propolis on the microbial plaque

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: all persons have teeth and without periodontal disease. Exclusion criteria: individuals who have: orthodontic brackets and band; partial dentures; more than three crown in the mouth and 4 or more than 4 milimeter pocket in 4 quadrant.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Technology Centre

Street address

University Research and Technology_Ganjafroz Street
_babol

City

babol

Postal code

4717641367

Approval date

2013-01-22, 1391/11/03

Ethics committee reference number

2006/30/پ/ز

Health conditions studied

1

Description of health condition studied

Periodontal disease

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Microbial plaque

Timepoint

2 weeks after the intervention.

Method of measurement

O'Leary's Plaque Index

Secondary outcomes

empty

Intervention groups

1

Description

Using toothpaste with propolis in the first group for 2 weeks (two times a day).Then They don't use for 48 hours and then using normal toothpaste for 2 weeks (two times aday)

Category

Treatment - Other

2

Description

Using normal toothpaste in the second group for 2 weeks (two times a day).Then they don't use for 48 hours and then using toothpaste with propolis for 2 weeks (two times aday)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Faculty of Dentistry

Full name of responsible person

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistant (Research and Technology), Babol
University of Medical Sciences

Full name of responsible person

Dr. Amrolah Mostafa Zadeh

Street address

Research and Technology, Babol University of Medical
Sciences_Ganjafroz Street _babol

City

babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Assistant (Research and Technology), Babol
University of Medical Sciences

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

Babol Faculty of Dentistry

Full name of responsible person

Dr. Majid Fereidooni

Position

Periodontist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Babol Faculty of Dentistry

Full name of responsible person

Amineh Amiri

Position

Dental students

Other areas of specialty/work

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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