

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation the effect of mouthwash containing propolis nanoparticles on plaque and gingival indices in fixed orthodontic patients.

Protocol summary

Study aim

Determining the effect of mouthwash containing propolis nanoparticles on plaque and gingival indices in fixed orthodontic patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 60 patients. The kitset.ir site was used for randomization.

Settings and conduct

The study will be performed on patients who refer to Babol Dental School for fixed orthodontic treatment. Plaque and gingival indices will be measured and recorded by the researcher in the periodontics department of the faculty in a basic state, and all patients are given three bottles of mouthwash that look exactly the same and the researcher and patient are not aware of the type of solution in it and the way of using it will be instructed. three weeks later, to evaluate the direction and extent of the effects of propolis nanoparticles, indices will be measured and recorded again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 13-19 years, appropriate oral health conditions (Plaque Index ≤ 2 and Gingival Index ≤ 2), complete and informed patient satisfaction.
exclusion criteria: the presence of any systemic disease, pregnancy and lactation for female participants, Smoking and alcohol consuming, periodontal disease, sever gingivitis and Severe plaque accumulation, history of any allergies to propolis or honey derivatives, history of taking antibiotics from two weeks and any mouthwash from one month before the intervention.

Intervention groups

After prophylaxis of all 60 patients' teeth and measurement of plaque and gingival indices of Ramford teeth and placement of orthodontic appliance in their mouth, all people will enter the intervention phase.

Main outcome variables

Plaque index ; Gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210906052393N1**

Registration date: **2021-10-25, 1400/08/03**

Registration timing: **prospective**

Last update: **2021-10-25, 1400/08/03**

Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Elahe hatamzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3525 3419

Email address

elaheehmz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-04, 1400/09/13

Expected recruitment end date

2022-03-05, 1400/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of mouthwash containing propolis nanoparticles on plaque and gingival indices in fixed orthodontic patients.

Public title

Evaluation the effect of mouthwash containing propolis nanoparticles on the gum and teeth condition of orthodontic patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 13-19 years Having proper oral hygiene (Plaque Index ≤ 2 , Gingival Index ≤ 2 the way of Sillness and Loe , Loe and Sillness) Complete and informed patient satisfaction

Exclusion criteria:

Existence of any systemic disease Pregnancy and lactation Smoking and alcohol consumption Existence of periodontal disease Having severe gingivitis and plaque accumulation History of any allergies to propolis or honey derivatives History of antibiotic consumption from two weeks before the intervention History of using any type of mouthwash during the month before the intervention

Age

From **13 years** old to **19 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People are divided into two groups of 30 people, so that in each group there will be 15 girls and 15 boys. The site kitset.ir is used to randomize the samples. In the Kitset site, from the number toolbox, select the option to generate random numbers. Then we request the production of 30 pieces from 1 to 30 in a non-sequential and non-repetitive way. The series of random numbers generated in the result box will be considered as the case number of the referring boy, the first 15 numbers will be in the case group and the next 15 numbers will be in the control group. We do the same for the referral girls again; In this way, we request the production of 30 pieces from 1 to 30 again without order and without repetition. The series of random numbers generated in the result box will be considered as the case number of the referring girl, the first 15 numbers will be in the case group and the next 15 numbers will be in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both types of mouthwashes are packaged with the same

appearance so that the patient and the researcher do not know the type of solution in the container; One type of mouthwash will belong to group A and the other to group B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol university of medical science

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.068

Health conditions studied

1

Description of health condition studied

Plaque index

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Gingival index

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plaque Index in Ramford teeth of fixed orthodontic patients

Timepoint

Before the intervention and one week after brushing and 21 days after starting to use mouthwash containing propolis nanoparticles.

Method of measurement

Standardized periodontal probe

2

Description

Gingival Index in Ramford teeth of fixed orthodontic patients

Timepoint

Before the intervention and one week after brushing and 21 days after starting to use mouthwash containing propolis nanoparticles

Method of measurement

Standardized periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of three bottles containing 250 ml mouthwash containing propolis nanoparticles prepared in the Department of Pharmacology at Babol University of Medical Sciences. Patients in this group rinse their mouth with this solution twice a day (Each time with 15 ml of pure mouthwash) after tooth brushing, for one minute and should do so for 21 consecutive days.

Category

Prevention

2

Description

Control group: Use of three bottles containing 250 ml mouthwash containing propolis particles prepared in the Department of Pharmacology at Babol University of Medical Sciences. Patients in this group rinse their mouth with this solution twice a day (Each time with 15 ml of pure mouthwash) after tooth brushing, for one minute and should do so for 21 consecutive days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic department of Babol dental faculty

Full name of responsible person

Elahe Hatamzadeh

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

elaheeehmz@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Valiolah Arash

Street address

خیابان گنج افروز

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

Vali-arash1344@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Valiolah Arash

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

Vali-arash1344@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Valioalah Arash

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

Vali-arash1344@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Elahe Hatamzadeh

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Ganjafrooz Ave.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3220 7918

Email

elaheeeehmz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available