Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
elaheeeehmz@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 و Gingival Index≤ 2 the way of Sillness and Loe و 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 departmet 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
elaheeeehmz@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