

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the microbial plaque removing effect of three methods of brushing and using brush and dentipur tabs and using brush and propolis mouthwash together for cleaning removable orthodontic appliances

Protocol summary

Study aim

Evaluating the microbial plaque removing effect of three methods of brushing and using brush and dentipur tabs together and using brush and propolis mouthwash together for cleaning removable orthodontic appliances

Design

A cross over randomized clinical trial with control group, enrolled between April 2019 and August 2019.

Settings and conduct

This study is designed in dental faculty of Hamadan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Removable orthodontic patients who have completely obeyed the instructions regarding appliance wear and oral hygiene and who have less than 30 plaque index. Patients who had systemic or immunodeficient disease would be excluded.

Intervention groups

Control group: brushing the orthodontic appliance for cleansing purpose Intervention group: brushing and using dentipur tablet for cleansing orthodontic appliance and brushing and using propolis mouthwash

Main outcome variables

The area of orthodontic appliance which have microbial plaque.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042253N2**

Registration date: **2019-03-07, 1397/12/16**

Registration timing: **prospective**

Last update: **2019-03-07, 1397/12/16**

Update count: **0**

Registration date

2019-03-07, 1397/12/16

Registrant information

Name

Homa Farhadifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3835 4250

Email address

homa.far1989@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the microbial plaque removing effect of three methods of brushing and using brush and dentipur tabs and using brush and propolis mouthwash together for cleaning removable orthodontic appliances

Public title

Cleansing effect of dentipur and brushing and propolis mouthwash for removable orthodontic appliances

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Full time wear of orthodontic appliance Tooth brushing with medium hardness brush and bass technique 3 times per day Plaque index lower than 30 One month of complete compliance with appliance wear and hygienic instruction regarding brushing the appliance age between 7-15 years old

Exclusion criteria:

Presence of systemic or immunodeficient diseases Poor compliance of appliance wear Poor compliance of hygienic instructions

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is designed as crossover. Each patient is allocated to each group in randomized and sequential order. Simple randomization was done with individual unit of randomization. Patient allocation and allocation concealment was conducted with numbers in sealed and opaque pockets.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan university of medical sciences

Street address

Shahid fahmide avenue

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.UMSHA.REC.1397.513

Health conditions studied

1

Description of health condition studied

Presence of microbial plaque on orthodontic appliance

ICD-10 code

B95.4

ICD-10 code description

Other streptococcus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Area of orthodontic removable appliance covered with microbial plaque.

Timepoint

Before intervention, 1 month after brushing, 1 month after combined use of brush and dentipur tablet and 1 month after combined use of brush and propolis mouthwash

Method of measurement

Microbial plaque is revealed by disclosing agent. Then a photograph is taken from orthodontic appliance and the area of disclosed region is calculated by aid of Image J software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: combined use of dentipur tablet (Helago-Pharma GmbH, Germany) and brush: patient floats his/her appliance in a solution including 1 dentipur tab + 200cc water for 3 minutes, then brushes the appliance, every night for 1 month.

Category

Prevention

2

Description

Intervention group: combined use of propolis mouthwash(30%extract,SorenTektoos,Mashhad) and brush: patient floats his/her appliance in a solution including 1 bushel (special for mouthwash) + 200cc water for 3 minutes, then brushes the appliance every night for 1 month.

Category

Prevention

3

Description

Control group: using brush: patient cleans his/her appliance with tooth brush (without toothpaste) every night for 1 month.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Hamadan university

Full name of responsible person

Homa Farhadifard

Street address

Fahmide avenue

City

Hamadan

Province

Hamadan

Postal code

654178-38741

Phone

+98 81 3838 1059

Email

Homa.far1989@gmail.com

2

Recruitment center

Name of recruitment center

Hamadan university dental clinic

Full name of responsible person

Homa farhadifard

Street address

Felestin squar

City

Hamadan

Province

Hamadan

Postal code

65176-59114

Phone

+98 81 3423 8989

Email

Homa.far1989@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Fahmide avenue

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0717

Email

S_bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Homa Farhadifard

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Fahmide Blvd.

City

Hamadan

Province

Hamadan

Postal code

65178-38677

Phone

+98 81 3835 4250

Fax

Email

homa.far1989@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Homa Farhadifard

Position

Assistant professor

Latest degree

Specialist

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Dentistry

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Fahmide Blvd.

City

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Province

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Postal code

65178-38677

Phone

+98 81 3835 4250

Fax**Email**

homa.far1989@gmail.com

65178-38677

Phone

+98 81 3835 4250

Fax**Email**

homa.far1989@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected data would be shared without patients name or identification data

When the data will become available and for how long

starting in 2020

To whom data/document is available

Academic institution

Under which criteria data/document could be used

The data can be used in larger, multicenter studies.

From where data/document is obtainableResearchers can assess data by emailing at
homa.far1989@gmail.com.**What processes are involved for a request to access data/document**

After emailing the request for data, the data would be sent in 1 week to the researcher.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Homa Farhadifard

Position

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Latest degree

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