Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Evaluating the microbial plaque removing effect of two methods of brushing and using brush and dentipur tabs together for cleaning removable orthodontic appliances

Design
A cross over randomized clinical trial with control group, enrolled between April 2018 and August 2018.

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

Main outcome variables
The area of orthodontic appliance which have microbial plaque.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150101020523N3**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

Registration date
2018-07-09, 1397/04/18

Registrant information

Name
Sepideh Soheilifar

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2264 2508

Email address
sepidehsoheilifar@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-09, 1397/01/20

Expected recruitment end date
2018-08-22, 1397/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the microbial plaque removing effect of two methods of brushing and using brush and dentipur tabs together for cleaning removable orthodontic appliances

Public title
Cleansing effect of dentipur and brushing 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

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 Fahmideh street

City

Hamadan

Province

Hamadan

Postal code

65178-38677

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.UMSHA.REC.1397.127

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

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 and brush

Category

Prevention

2

Description

Control group: using brush

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic department of dental faculty of Hamadan University of Medical Sciences

Full name of responsible person

Sepideh Soheilifar

Street address

Shahid Fahmideh

City

Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1086
Fax
+98 81 3838 1085
Email
se.soheilifar@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
Shahid Fahmideh Street
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
Sepideh Soheilifar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmideh street
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1086
Email
se.soheilifar@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Sara Soheilifar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmideh street
City
Hamadan
Province
Hamadan
Postal code
65178-38677
Phone
+98 81 3838 1086
Email
sara_soheilifar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Sepideh Soheilifar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Fahmideh Street
City
Hamadan
Province
Hamadan

Postal code
65178-38677
Phone
+98 81 3838 1086
Fax
Email
se.soheilifar@gmail.com
Web page address

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, muticenter studies.
From where data/document is obtainable
Researchers can assess data by emailing at se.soheilifar@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