

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
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Saeed Bashirian  
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**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**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

#### Contact

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**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, multicenter 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**