

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effect of application of nano-silver particles in acrylic base plate of orthodontic removable retainers on oral microflora

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effect of adding nano silver particles on acrylic base plate of orthodontic removable Retainers on the oral microbial flora. After fixed orthodontic treatment, 60 patients were randomly placed in two groups; group 1 (control group) received conventional removable acrylic plate. Group 2 (intervention group); this group received removable acrylic plate containing silver nano particles. Inclusion criterion: patients who complete their fixed orthodontic treatment and needs removable retainer. Exclusion criteria: smoking habits; presence of active caries or periodontal pockets; systemic diseases; antibiotics; prosthetic appliances. When the removable plate was delivered to the patient and 50 days after, dental plaque samples were taken from patients and cultured. The results were analyzed using paired T-test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309239086N2**

Registration date: **2013-11-09, 1392/08/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-11-09, 1392/08/18

##### Registrant information

##### Name

Nasrin Farhadian

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1835 4017

##### Email address

farhadian@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

School of Dentistry, Hamedan University of Medical Sciences

##### Expected recruitment start date

2013-11-01, 1392/08/10

##### Expected recruitment end date

2014-04-21, 1393/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of application of nano-silver particles in acrylic base plate of orthodontic removable retainers on oral microflora

##### Public title

Antimicrobial effect of nano silver particles

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criterion: patients who complete their fixed orthodontic treatment and needs removable retainer. Exclusion criteria: smoking habits; presence of active caries or periodontal pockets; systemic diseases; antibiotics and prosthetic appliances.

##### Age

No age limit

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamedan university of medical sciences

##### Street address

Hamadan , university of medical sciences

##### City

Hamadan

##### Postal code

#### Approval date

2013-10-29, 1392/08/07

#### Ethics committee reference number

2401/9/35/16/د/پ

## Health conditions studied

### 1

#### Description of health condition studied

Dental caries

#### ICD-10 code

K02

#### ICD-10 code description

Dental caries

## Primary outcomes

### 1

#### Description

Streptococcus mutans bacteria

#### Timepoint

When the removable plate was delivered to the patient and 50 days after

#### Method of measurement

cfu/saliva culture

### 2

#### Description

Candida albicans

#### Timepoint

At the end of study

#### Method of measurement

Colony count

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: received conventional orthodontic retainer and The patient was instructed to use her/his retainer full-time except when eating and brushing. Oral hygiene will be instructed for all patients, including brushing with toothpaste containing fluoride . Dental biofilm sample of upper arch at the time of retainer delivery and after 50 days use of retainer(end of study) will be obtained for colony count and evaluated in culture medium. Also at the end of study upper removable retainer will be sent for candida assessment.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: similar as control group but they will receive removable orthodontic retainer containing nano silver particle and patient was instructed to use her/his retainer full-time except when eating and brushing. Oral hygiene will be instructed for all patients, including brushing with toothpaste containing fluoride . Dental biofilm sample of upper arch at the time of retainer delivery and after 50 days use of retainer(end of study) will be obtained for colony count and evaluated in culture medium. Also at the end of study upper removable retainer will be sent for candida assessment.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental school of Hamadan university , private orthodontic clinic

##### Full name of responsible person

Nasrin Farhadian

##### Street address

Dental school of Hamadan university , Shahid Fahmide Blvd. Hamadan

##### City

Hamedan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Faculty of dentistry, Hamedan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Faculty of Dentistry, Hamedan University of Medical Sciences, Shahid fahmide blv

**City**

Hamedan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Faculty of dentistry, Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Hamedan University of Medical Sciences, Faculty of Dentistry

**Full name of responsible person**

Nasrin Farhadian

**Position**

Associated professor

**Other areas of specialty/work****Street address**

Orthodontic dept., Dental faculty, Hamadan University of Medical Sciences , Shahid Fahmide blv.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*