

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Clinical improvement of gingival hyperplasia with mouthwashes chlorhexidine vs persica and powered brush in fixed orthodontic cases

#### Protocol summary

##### Summary

Fixed orthodontic patients with minimum 2 teeth with gingival hyperplasia and inflammation (without history of anticonvulsant ,antibiotic drugs and antibacterial mouthwashes during last 6 months , without presence of calcolous or bonding agent excess) are randomly allocated into 4 groups . Group 1(as control)- receive oral hygiene instruction , orthodontic toothbrush Oral B and toothpaste with 1450 ppm fluoride .2-the same as group 1 but receive power brush Oral B . 3- the same as group 1 and additionally get Persica mouthwash (according to manufacture instructions) .4- The same as group 3 but receive Chlorhexidine mouthwash. They do instructions for 2 weeks. Gingival & plaque indices , BOP and gingival hyperplastic index are measured at the start and at the end of study . ANOVA , Mann-whitney & Friedmann tests are used for analysis

#### General information

##### Acronym

persica vs chlorhexidine vs power brush

##### IRCT registration information

IRCT registration number: **IRCT201202209086N1**

Registration date: **2012-04-30, 1391/02/11**

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

Last update:

Update count: **0**

##### Registration date

2012-04-30, 1391/02/11

##### 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

Research center of Dental faculty , Hamadan university of medical sciences,

##### Expected recruitment start date

2012-04-30, 1391/02/11

##### Expected recruitment end date

2013-04-30, 1392/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical improvement of gingival hyperplasia with mouthwashes chlorhexidine vs persica and powered brush in fixed orthodontic cases

##### Public title

Clinical improvement of gingival hyperplasia with chlorhexidine , persica and powered brush in fixed orthodontic cases

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion :under fixed orthodontic treatment , minimum 2 teeth with gingival enlargement and inflammation.

Exclusion :history of anticonvulsant drugs , history of antibiotic therapy during last 6 months , history of receiving antibacterial mouthwashes during last 6 month , presence of calcolous or bonding agent excess.

##### Age

From **12 years** old to **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

**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 Research Center ,Hamadan  
University of Medical Sciences

**Street address**

Hamadan , blv. shahid fahmide ,Hamadan University  
of medical sciences

**City**

Hamadan

**Postal code**

**Approval date**

2012-04-21, 1391/02/02

**Ethics committee reference number**

4943/9/35/16/د/پ

## Health conditions studied

### 1

**Description of health condition studied**

Gingival enlargement

**ICD-10 code**

K06.1

**ICD-10 code description**

Gingival enlargement

## Primary outcomes

### 1

**Description**

Bleeding on Probing(BOP)

**Timepoint**

Start at case selection phase , 2 weeks after treatment  
protocols

**Method of measurement**

According to indices descriptions using periodontal probs

### 2

**Description**

plaque index

**Timepoint**

Start at case selection phase , 2 weeks after treatment  
protocols

**Method of measurement**

According to indices descriptions using periodontal probs

### 3

**Description**

Gingival hyperplastic index

**Timepoint**

Start at case selection phase , 2 weeks after treatment  
protocols

**Method of measurement**

According to indices descriptions using periodontal probs

### 4

**Description**

Gingival index

**Timepoint**

Start at case selection phase , 2 weeks after treatment  
protocols

**Method of measurement**

According to indices descriptions using periodontal probs

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Patient recieves toothbrush , toothpaste(control) , and  
oral hygiene instruction and requested to do instructions  
for 2 weeks.

**Category**

Treatment - Drugs

### 2

**Description**

Patient recieves powerde toothbrush , toothpaste , and  
oral hygiene instruction and requested to do instructions  
for 2 weeks.

**Category**

Treatment - Drugs

### 3

**Description**

Patient receives toothbrush , toothpaste , and oral hygiene instruction and persica mouthwash requested to do instructions according to manufacture for 2 weeks.

**Category**

Treatment - Drugs

**4**

**Description**

Patient receives toothbrush , toothpaste , and oral hygiene instruction and chlorhexidine mouthwash requested to do instructions according to manufacture for 2 weeks.

**Category**

Treatment - Drugs

**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.

**City**

Hamadan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Research centre of Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Heidar Tavilani

**Street address**

Hamedan University of Medical Sciences , shahid fahmide blvd.

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research centre of 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**

Dental faculty, Hamadan University of Medical Sciences

**Full name of responsible person**

Nasrin Farhadian

**Position**

associated professor

**Other areas of specialty/work**

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**Web page address****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*