

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

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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