

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the effect of fixed orthodontic devices with using Chlorhexidin mouth rins on vitality of oral mucosa cells in clinical conditions.

Protocol summary

Study aim

Determination of effects of fixed orthodontic treatment together with Chlorhexidine mouth wash on the vitality of cells of oral mucosa in vivo.

Design

In this research 30 patients undergoing orthodontic treatment are indicated. Participants should have orthodontic treatment. Sampling is done by scrubbing oral mucosa ,before beginning of treatment, One month later and two weeks after that using mouth rins in patients with gingivitis. Study is done in-vivo condition. Patients sign Consent Form.

Settings and conduct

This study was performed in orthodontic department of Islamic Azad University Dental Branch of Tehran. Sampling is done by scrubbing oral mucosa ,before beginning of treatment, One month later and two weeks after that using mouth rins in patients with gingivitis. Study is done in-vivo condition. Patients sign Consent Form.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Have a indication for fixed orthodontics treatment for both jaws Exclusion criteria: age rang 12-35 years ;No systemic disease ;No use cigarette and alcohol ;No previous experience of orthodontic treatment ;Using mouth rinse with gingivitis.

Intervention groups

In this study, Chlorhexidine is as a intervention. This mouth wash is used to reduce inflammation of the gum and has not been specifically prescribed for it

Main outcome variables

Vitality of cells of oral mucosa.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161205031250N3**

Registration date: **2017-12-25, 1396/10/04**

Registration timing: **retrospective**

Last update: **2017-12-25, 1396/10/04**

Update count: **0**

Registration date

2017-12-25, 1396/10/04

Registrant information

Name

Fariborz Amini

Name of organization / entity

Islamic Azad University Of Medical Science Dental School

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 1619

Email address

f_aminei@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Personal experiences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2017-11-06, 1396/08/15

Trial completion date

empty

Scientific title

Evaluation of the effect of fixed orthodontic devices with using Chlorhexidin mouth rins on vitality of oral mocusa cells in clinical conditions.

Public title

Effect using chlorhexidin on oral mocusa.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who indication for fixed orthodontics treatment for both jaws In age rang 12-35 years

Exclusion criteria:

No systemic disease No use cigarette and alcohol No previous experience of orthodontic treatment Using mouth rinse with gingivitis

Age

From **12 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Islamic Azad University Dental Branch of Tehran

Street address

No.4, Neyestan 9.,Pasdaran Ave.

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR-IAU.DENTAL.REC.1395,27

Health conditions studied**1****Description of health condition studied**

Patients with Fixed Orthodontics Appliance

ICD-10 code

Z46.4

ICD-10 code description**Primary outcomes****1****Description**

Vitality of Oral mocousal cell

Timepoint

Before treatment ,1 month after treatment and 2 weeks after treatment

Method of measurement

Number of cells with microscope

Secondary outcomes

empty

Intervention groups**1****Description**

Patients use CHX Mouthwash 0/012% BID for 30 seconds for 2 weeks after 1 month of Orthodontic treatment.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Orthodontics , Islamic Azad University Dental Branch of Tehran

Full name of responsible person

Mahyar Mahvash Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Islamic Azad University
Dental Branch of Tehran

Full name of responsible person

mahyar mahvash mohammadi

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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

Vice chancellor for research Islamic Azad University
Dental Branch of Tehran

Proportion provided by this source

1

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**

Department of Orthodontics, Faculty of Dentistry ,
Islamic Azad University of Tehran

Full name of responsible person

Mahyar Mahvash Mohammadie

Position

Post graduate student of orthodontics

Latest degree

Medical doctor

Other areas of specialty/work

Orthodontics

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Contact**Name of organization / entity**

Faculty of Dentistry , Islamic Azad University of
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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact**Name of organization / entity**

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Mahyar Mahvash Mohammadi

Position

Post graduate student of Orthodontics

Latest degree

Medical doctor

Other areas of specialty/work

orthodontics

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available