Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

Determinaton 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 scrubing 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 orthodentic department of Islamic Azad University Dental Branch of Tehran.Sampling is done by scrubing 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 jawsn 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 Sciense Dental School

Country

Iran (Islamic Republic of)

Phone

+98 21 2212 1619

Email address

f_amini@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
Befor 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
Orthodentics

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Full name of responsible person
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Professor

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Specialist

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Orthodontics

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Person responsible for updating data

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Post graduat student of Orthodontics

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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