

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

A clinical trial to compare the effectiveness of mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan with chlorhexidine and fluoride mouthwash in patients undergoing fixed orthodontic treatment.

Protocol summary

Study aim

To compare the effectiveness of mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan with chlorhexidine and fluoride mouthwash in patients undergoing fixed orthodontic treatment.

Design

Forty-five patients whose undergoing orthodontic treatment, two blind parallel group randomised clinical trial

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, the participants and responsible for data collection are unaware the kind type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Undergoing fixed orthodontic treatment; age range of 14-18 years. Exclusion criteria: History or presence of periodontal disease; history of allergies.

Intervention groups

Intervention Group I will receive mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan daily for two weeks, Intervention Group II will receive chlorhexidine 1% mouthwash (Behsa-Iran) daily for two weeks and Intervention Group II will receive fluoride 0.05 % mouthwash (Oral B, Ireland) daily for two weeks.

Main outcome variables

Evaluation and comparison of the Streptococcus mutans population, gingival index, plaque index and gingival bleeding index before and 4 weeks after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190821044572N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Zahra Bizhannzhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

bizhannz921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan with chlorhexidine and fluoride mouthwash in patients undergoing fixed orthodontic treatment.	
Public title	The effectiveness of mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan therapy on tooth decay.
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	Undergoing fixed orthodontic treatment Age range of 14-18 years
Exclusion criteria:	History or presence of periodontal disease History of allergies
Age	From 14 years old to 18 years old
Gender	Both
Phase	2-3
Groups that have been masked	- Care provider - Outcome assessor
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	Forty-five patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, randomly base on Randomizer.org website assigned three intervention groups. A code was allocated to each of the participants.
Blinding (investigator's opinion)	Double blinded
Blinding description	Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this double-blind study, the participants and responsible for data collection are unaware the kind type of treatment.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	Name of ethics committee Ethics Committee of Mashhad University of Medical Sciences Street address Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street City Mashhad Province Razavi Khorasan Postal code 9195965919 Approval date 2019-04-23, 1398/02/03 Ethics committee reference number IR.MUMS.DENTISTRY.REC.1398.108
Health conditions studied	
<u>1</u>	
Description of health condition studied	Fixed orthodontic
ICD-10 code	Z46.4
ICD-10 code description	Fitting and adjustment of orthodontic device
Primary outcomes	
<u>1</u>	
Description	Gingival index
Timepoint	Before and 4 weeks after the intervention
Method of measurement	Base on Silness-Löe plaque index
<u>2</u>	
Description	Plaque index
Timepoint	Before and 4 weeks after the intervention
Method of measurement	Base on Silness-Löe plaque index
<u>3</u>	
Description	Gingival bleeding index
Timepoint	Before and 4 weeks after the intervention
Method of measurement	Base on Silness-Löe plaque index
Secondary outcomes	

1

Description

Streptococcus mutans population

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Based on mineral trioxide aggregate (MTA) method

Intervention groups

1

Description

Intervention group: Intervention Group I will receive mouthwash that contains amorphous calcium phosphate nanoparticles in a chitosan daily for two weeks.

Category

Prevention

2

Description

Intervention group: Intervention Group II will receive chlorhexidine 1% mouthwash (Behsa-Iran) daily for two weeks.

Category

Prevention

3

Description

Intervention group: Intervention Group II will receive fluoride 0.05 % mouthwash (Oral B, Ireland) daily for two weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Zahra Bezhannezhad

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3883 2300

Email

Bizhannz921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street

City

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Province

Razavi Khorasan

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1394491388

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Bezhannezhad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

City

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Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Bezhannezhad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact

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Full name of responsible person
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Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Zahra Bezhannezhad provides the analysis code to the applicants via email: Bizhannz921@mums.ac.ir

What processes are involved for a request to access data/document

Applicants can respond to the email of the respondent and receive a response within a week.

Comments