

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**1****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**1****Description of health condition studied**

Fixed orthodontic

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes**1****Description**

Gingival index

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Base on Silness-Löe plaque index

2**Description**

Plaque index

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Base on Silness-Löe plaque index

3**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

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9177948959

Phone

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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
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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

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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
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Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

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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