

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of zinc(1%), chlorhexidine (0/2%)and propolis mouthwashes on periodontal indices of children undergoing preventive orthodontic treatment

Protocol summary

Study aim

Determining the effect of three mouthwashes containing zinc ,chlorhexidine(0/2%) and propolis on periodontal indices in children undergoing preventive orthodontic treatment

Design

clinical trial without blinded group and crossover designed of 16 patients

Settings and conduct

16 children 8 to 12 years old will be selected from the patients of dental school of Qazvin University of Medical Sciences who use mandible lingual arch. After presenting the necessary explanations, written consent will be taken from the parents. each of Zinc ,Propolis and Chlorhexidine Mouthwashes will be used for a period of one week, after which the PI and GI indices on the deciduous teeth will be measured. patients will be asked to brush their teeth three times a day as instructed. The mouthwash is gargle for 30 seconds half an hour after using the toothbrush. After using the mouthwashes, they dont wash their mouth and also dont eat anything. Avoid using toothpaste containing fluoride for an hour before using mouthwashes. After using each mouthwash , it should be a period of two weeks as washout

Participants/Inclusion and exclusion criteria

16 children 8 to 12 years old with lingual arch appliance in their mandible Inclusion criteria: Patient willingness to cooperate with research Do not suffer from disease that weaken the immune system Do not suffer from various systemic disease Do not receive antibiotics at least one month before and during the research priod Do not use mouthwash in the past month Absence of periodontitis and do not receive periodontal treatments in the last 6 months Exclusion criteria: Sensivity to mouthwashes Participants are reluctant to continue the process of using mouthwashes

Intervention groups

All of participanta recieve three types of mouthwashes

Main outcome variables

Decrease of plauqe index;Decrease of gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052460N1**

Registration date: **2021-09-20, 1400/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

zahra fotouhi qazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3357 1036

Email address

z.fotohighazvini@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-11, 1400/05/20

Expected recruitment end date

2021-09-29, 1400/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of zinc(1%), chlorhexidine (0/2%)and propolis mouthwashes on periodontal indices of children undergoing preventive orthodontic treatment

Public title

Comparing the effect of three types of mouthwashes on periodontal indices of children undergoing orthodontic treatment

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient willingness to cooperate with research Do not suffer from disease that weaken the immune system Do not suffer from various systemic disease Do not receive antibiotics at least one month before and during the study period Absence of periodontitis and receiving periodontal treatment in the last six months

Exclusion criteria:

Sensitivity to mouthwashes Participants are reluctant to continue the process of using mouthwashes

AgeFrom **8 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **16****Randomization (investigator's opinion)**

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical Sciences

Street address

No.69 ,Azimian Ave.,Tehranqadim St.,Qazvin

City

Qazvin

Province

Qazvin

Postal code

3418683746

Approval date

2021-08-11, 1400/05/20

Ethics committee reference number

IR.QUMS.REC.1400.220

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

periodontal indices

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

plaque index

Timepoint

Beginning of research,7 days after using each mouthwash,with two weeks washout

Method of measurement

sillness and loe,with periodontal probe

2**Description**

gingival index

Timepoint

Beginning of research,7 days after using each mouthwash,with two weeks washout

Method of measurement

Examination with periodontal probe

Secondary outcomes

empty

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

Intervention group: Chlorhexidine,zinc, propolis mouthwashes

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Qazvin university of medical science

Full name of responsible person

Zahra Foyouhi qazvini

Street address

No.69, Azimian Ave.,Tehranqadim St.,Qazvin,Iran

City

Qazvin

Province

Qazvin

Postal code

3418683746

Phone

+98 28 3357 1036

Email

z.fotohighazvini@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. seyed mahdi mirhashemi

Street address

Shahid beheshti Blv.

City

Qazvin

Province

Qazvin

Postal code

1391134156

Phone

+98 28 3333 7006

Email

sm.mirhashemi@qums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Zahra Fotouhiqazvini

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

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Fotouhiqazvini

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No.69,Azimian Ave.,Tehranqadim St.,Qazvin,Iran

City

Qazvin

Province

Qazvin

Postal code

3417683746

Phone

+98 28 3357 1036

Email

z.fotohighazvini@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Fotouhiqazvini

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No.69,Azimian Ave.,Tehranqadim St.,Qazvin,Iran

City

Qazvin

Province

Qazvin

Postal code

3417683746

Phone

+98 28 3357 1036

Email

zarafth@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Fotouhiqazvini

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No.69,Azimian Ave.,Tehranqadim St.,Qazvin,Iran

City

Qazvin

Province

Qazvin

Postal code

3417683746

Phone

+98 28 3357 1036

Email

z.fotohighazvini@qums.ac.ir

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data containing PI and GI of all participants can be shared after unidentified individual

When the data will become available and for how long

Start access after the article is published

To whom data/document is available

everybody

Under which criteria data/document could be used

other researchs

From where data/document is obtainable

Zahra Fotouhiqazvini,email:zarafth@yahoo.com

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

Sending a request email

Comments