

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison the effect of persica and chlorhexidine mouthwash in reducing salivary and plaque streptococcus mutans in primary school children.

Protocol summary

Summary

In this study we aimed to compare persica herbal mouthwash effects in reduction of streptococcus mutans in saliva and in plaque of primary school children with chlorhexidine. This randomized clinical trial was done on 50 primary school (6 to 12 years) children who were living in Fayyaz bashkh Mashhad child care center, Hashemi nezhad center, Fereshtegan center and Shahid Beheshti center who have moderate and weak oral hygiene but high caries risk and did not use of mouthwash and antibiotic in 3 weeks ago. Children randomly assigned to one of the persica or chlorhexidine groups. At baseline samples from saliva and plaque were collected. After one week use of mouthwashes the samples were repeated. The streptococcus mutans count in saliva and plaque as well as saliva PH and plaque index were recorded in both times.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030532881N1**

Registration date: **2017-06-15, 1396/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-15, 1396/03/25

Registrant information

Name

Zahra Mohammadzadeh

Name of organization / entity

Mashhad dental school

Country

Iran (Islamic Republic of)

Phone

+98 51 3662 9015

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mohammadzadehz@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of persica and chlorhexidine mouthwash in reducing salivary and plaque streptococcus mutans in primary school children.

Public title

Comparison the effect of persica and chlorhexidine mouthwash.

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: primary school children with high caries risk ; without use of antibiotic and mouthwash in 3 weeks ago. exclusion criteria: use of antibiotic and mouthwash ; lack of cooperation

Age

From **6 years** old to **12 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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

Mashhad univer sity of medical sciences,Daneshgah St. - Mashhad - Iran

City

Mashhad

Postal code

91735

Approval date

2016-06-29, 1395/04/09

Ethics committee reference number

IR.mums.sd.REC.1395.139

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

k02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes

1

Description

streptococcus mutans counts in dental plaque

Timepoint

at baseline and after 1 week ude of mouthwash

Method of measurement

microbial culture

2

Description

streptococcus mutans counts in saliva

Timepoint

at baseline and after 1 week ude of mouthwash

Method of measurement

bacterial cilture

3

Description

dental plaque

Timepoint

at baseline and after 1 week ude of mouthwash

Method of measurement

Loe&Sillness scale

4

Description

saliva ph

Timepoint

at base line and after 1 week use of mouthwash

Method of measurement

ph meter

Secondary outcomes

empty

Intervention groups

1

Description

in intervention group Persica mouthwash was prescribed for 25 children who have weak and moderate oral hygiene but high caries risk .mouthwash was diluted by pharmacist before prescription ,according to factory instruction .this means that one drop of Persica in one cc water and the children were asked to rinse twice a day with 15 mlit for 60 seconds. at baseline samples from saliva and plaque were collected. After one week use of mouthwashes the samples were repeated. The streptococcus mutans counts in saliva and plaque as well as saliva PH and plaque index were recorded in both times.

Category

Prevention

2

Description

in control group 0.12% Chlorhexidine mouthwash was prescribed for 25 children who have weak and moderate oral hygiene but high caries risk and the children were asked to rinse once a day with 15 mlit for 60 seconds.at baseline samples from saliva and plaque were collected.

After one week use of mouthwashes the samples were repeated. The streptococcus mutans counts in saliva and plaque as well as saliva PH and plaque index were recorded in both times.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

fereshtegan house

Full name of responsible person

MS Ramezan zade

Street address**City**

Mashhad

2

Recruitment center

Name of recruitment center

fayyaz bakhsh home

Full name of responsible person

Ms Molayi

Street address**City**

Mashhad

3

Recruitment center

Name of recruitment center

shahid beheshti center

Full name of responsible person

Mr Hashemi

Street address**City**

Mashhad

4

Recruitment center

Name of recruitment center

Hashemi nezhad center

Full name of responsible person

Ms Ghorbani

Street address**City**

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Research chancellor of Dental School of Mashhad

University of Medical Sciences , Malihe Razm Avar

Street address

Mashhad University of Medical Sciences, Vakil Abad Bolvard, Mashhad, Iran

City

Mashhad

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of dentistry , Mashhad University of Medical Sciences

Full name of responsible person

Zahra Mohammadzadeh

Position

assistant professor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

pedodontist

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Full name of responsible person

Zahra Mohammadzadeh

Position

Pedodontist

Other areas of specialty/work

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City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty