

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effect of photodynamic therapy by Curcumin and Orthokine mouthwash on Streptococcal Mutans in Fix Orthodontic Patients

Protocol summary

Study aim

Considering the importance of caries prevention during orthodontic treatment and the rate of caries, this study investigates the effects of photodynamic therapy by curcumin on the accumulation of Streptococcus mutans as the main cause of tooth decay and compares it with conventional orthokine mouthwash.

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 2-3 on 105 patients. Excel software rand function was used for randomization.

Settings and conduct

The present study is an interventional study in which the effect of orthokine mouthwash and photodynamic therapy by curcumin on Streptococcus mutans in patients undergoing orthodontic treatment in the specialized department of the Faculty of Dentistry of Kurdistan University of Medical Sciences will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patient informed consent to participate in the study • Those who can receive fixed orthodontic treatment and can cooperate. • People who have had two to three months since starting orthodontic treatment • Individuals who did not receive any plaque removal treatment prior to enrollment. Exclusion criteria: Poor cooperation Periodontal diseases pregnant women Having systemic diseases affecting the quality and quantity of dental plaque Taking antibiotics History of radiotherapy A large number of decayed teeth

Intervention groups

1. Health controllers using toothbrushes and toothpaste containing fluoride alone (as a control group) 2. Hygiene controllers using toothbrush, toothpaste and orthokine mouthwash 3. Hygiene controllers using toothbrush and toothpaste with photodynamic therapy using curcumin

Main outcome variables

Determination of Streptococcus mutans

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201125049490N1**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **retrospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Elnaz Hajhemati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3322 7065

Email address

elnazhematy98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2019-11-22, 1398/09/01

Actual recruitment end date

2020-05-21, 1399/03/01

Trial completion date

2020-09-22, 1399/07/01

Scientific title

Comparision of the effect of photodynamic therapy by Curcumin and Orthokine mouthwash on Streptococcal Mutans in Fix Orthodontic Patients

Public title

effect of photodynamic therapy by Curcumin mouthwash on Streptococcal Mutans

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient informed consent to participate in the study can receive fixed orthodontic treatment and can cooperate. People who have had two to three months since starting orthodontic treatment Individuals did not receive any plaque removal treatment prior to enrollment.

Exclusion criteria:

Poor cooperation Periodontal diseasespregnant womenHaving systemic diseases affecting the quality and quantity of dental plaque Taking antibiotics History of radiotherapy A large number of decayed teeth

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

The conditions for studying and performing the plan will be fully explained to the patients. In the next step, randomization is divided into 3 groups (ABC) in random blocks using triple number tables. Then a pack containing 105 cards with one of the letters A = intervention group (35 pieces), B = control group B (35 pieces) and the third group C control B (35 pieces) is considered so that patients from within the package Randomly select a card and enter one of the groups according to the Latin letter. In this way, 35 people are assigned to each control and intervention group. Sampling is done in parallel in 3 groups until the number of samples is completed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kurdistan Medical Sciences Ethics Committee

Street address

Pasdaran Street. Kurdistan University of Medical Sciences. dental College

City

SANANDAJ

Province

Kurdistan

Postal code

6616958452

Approval date

2020-11-16, 1399/08/26

Ethics committee reference number

IR.MUK.REC.1399.213

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

Patients undergoing fixed orthodontic treatment

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

photodynamic therapy with curcumin

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

By visible blue LED light

Secondary outcomes**1****Description****Timepoint****Method of measurement****Intervention groups****1****Description**

Intervention group: Health controllers using toothbrush and toothpaste and photodynamic therapy using

curocumin
Category
Treatment - Devices

2

Description
Control group: Hygiene controllers using toothbrush, toothpaste and ortokin mouthwash

Category
Treatment - Devices

3

Description
Control group: Hygiene controllers using toothbrushes and toothpaste

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Dentistry, Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Ilnaz Haj Hemmati
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Pasdarán Street. Kurdistan Dental School of Medical Sciences
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences
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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
Sanandaj University of Medical Sciences
Proportion provided by this source
50
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
Sanandaj University of Medical Sciences
Full name of responsible person
Dr. Ilnaz Haj Hemmati
Position
asistans profossor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data**Contact****Name of organization / entity**

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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