Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of antimicrobial photodynamic therapy effects of orthodontic resin acrylic containing Curcumin-nisin poly-lactic acid nanoparticles (CurNisNp): A randomized, double-blind case-control clinical trial

Protocol summary

Study aim

Determining the antimicrobial effect of acrylic resin containing 5% CurNisNp on the Streptococcus mutans population in patients with removable acrylic resin appliances

Design

Two-arm parallel group, double-blind, randomized, on 24 patients (case + intervention group + comparison group). A simple random method was used for randomization using a sealed envelope.

Settings and conduct

Field: Antimicrobial photodynamic therapy Place: Faculty of Dentistry, Shahid University, and Department of Microbiology, TUMS. Patients are divided into 2 intervention (A) and comparison (B) groups (n=12). Before the intervention, saliva was taken to determine the load of S. mutans (SM), and the appliance with 5% CurNisNp was applied and exposed to LED (450 nm, 5 min) (photodynamic therapy). Then saliva is collected for determination of the load of SM. In the monthly visit before and after irradiation, the load of SM is determined. Group B was the same as Group A, except that the appliance did not have the nanoparticles and they did not receive LEDs. The Microbiologist and orthodontist are blinded by coding the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - At least 20 permanent teeth Exclusion criteria: Extensive fillings, Underlying diseases, Periodontal diseases, Antibiotic use in less than 1 month, and Absence of S. mutans in Baseline

Intervention groups

- The intervention group includes patients who receive removable appliances containing 5% curcumin-nisin poly-lactic acid nanoparticles and LED radiation in monthly periodic visits (photodynamic therapy) for 6 months. - The comparison group includes patients who receive the removable appliances without curcumin-nisin poly-lactic acid nanoparticles and without LED radiation in monthly periodic visits (photodynamic therapy) for 6 months.

Main outcome variables

Changes in the amount of Streptococcus mutans in saliva samples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230223057507N1**
Registration date: **2023-06-04, 1402/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-04, 1402/03/14**
Update count: **0**

Registration date

2023-06-04, 1402/03/14

Registrant information

Name
Abbas Bahador
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8895 5810
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2025-04-04, 1404/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of antimicrobial photodynamic therapy effects of orthodontic resin acrylic containing Curcumin-nisin poly-lactic acid nanoparticles (CurNisNp): A randomized, double-blind case-control clinical trial

Public title

Investigating the effect of photodynamic therapy in reducing caries in removable orthodontics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Has at least 20 permanent teeth Treatment plan with movable orthodontic appliance (acrylic).

Exclusion criteria:

Extensive tooth fillings Removable denture Underlying diseases Periodontal diseases Tooth loss due to extensive caries Use of antibiotics in less than 1 month Lack of Streptococcus mutans in the screening phase (Base line)

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **7**

1mL of unstimulated saliva

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization, Randomization unit: individual, Randomization tool: sealed envelope,

Blinding (investigator's opinion)

Double blinded

Blinding description

Number and coding for groups and patients in such a way that the microbiologist and orthodontist are not aware of the assigned code for groups and individuals.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee ofTehran University of Medical Sciences

Street address

Enghelab Ave.

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1417613151

Approval date

2023-02-12, 1401/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.754

Health conditions studied

1

Description of health condition studied

orthodontics

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changing the population of effective bacteria in dental caries

Timepoint

Measuring the population of Streptococcus mutans at the beginning of the study (before the start of the intervention) and 30, 60, 90, 120, 150 and 180 days after using the removable acrylic resin appliance

Method of measurement

Counting of bacterial population via serial dilution

Secondary outcomes

empty

Intervention groups

1

Description

The device used in the intervention group is a removable appliance made of acrylic methacrylate (Sigma-Aldrich) containing 5% curcumin-nisin poly-lactic acid nanoparticles. The curcumin, nisin, and lactic acid

nanoparticles are obtained from Merck and Sigma-Aldrich, Germany. After making a mold of the patient's mouth and creating the removable appliance with the nanoparticles, the appliance is immediately placed in the patient's mouth, and the mouth is exposed to LED radiation (wavelength 450 nm, 5 minutes) for photodynamic therapy. Saliva is collected from the patient after the treatment. The removable appliance remains in the patient's mouth for 6 months, and at monthly visits before and after LED irradiation, unstimulated saliva preparation is conducted to determine the population of S. mutans.

Category

Treatment - Devices

2

Description

In the comparison group, a removable appliance was used as the device. The appliance was manufactured using only acrylic methacrylate (made by Sigma-Aldrich, Germany). After making a mold of the patient's mouth, the removable appliance was placed in the patient's mouth, and saliva was obtained. The removable appliance remained in the patient's mouth for 6 months, and at monthly visits, saliva preparation was conducted to determine the population of S. mutans.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

aculty of Dentistry, Shahid University

Full name of responsible person

Dr. Roghayeh Ghorbanzadeh

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Sponsors / Funding sources

1

Sponsor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Abbas Bahador

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Non-identifiable personal data of participants is not important for publication.
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
Not applicable