

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

A clinical trial to compare the effectiveness of photodynamic therapy with light and laser on streptococcus mutans in patients undergoing fixed orthodontic treatment

Protocol summary

Study aim

To compare the effectiveness of photodynamic therapy with light and laser on streptococcus mutans in patients undergoing fixed orthodontic treatment

Design

A randomized, clinical trial based on random number table

Settings and conduct

Patients undergoing fixed orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, in a not blind study, are aware of the type of Streptococcus mutans treatment.

Participants/Inclusion and exclusion criteria

Patients undergoing fixed orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry

Intervention groups

Intervention Group I will receive chlorine-based photodynamic therapy with wavelength of 660 nm and red laser diodes power of 200 μ . Intervention Group II will be subjected to toluidine blue-mediated photodynamic therapy with wavelength of 480 nm and light blue LED power of 2000-4000 mw/cm. Intervention Group III will receive photodynamic therapy using Emondo as photocatalytic material with wavelength of 810 nm and laser power of 200 μ . The three groups receive the interventions for 45 second once a week for 4 weeks. The control group does not receive photodynamic therapy.

Main outcome variables

Evaluation and comparison of the effectiveness of photodynamic therapy on the Streptococcus mutans count in 4 groups, which are sampled by sterile swabs from 6 anterior teeth and measured by microbial counting before and 4 weeks after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037270N1**

Registration date: **2017-12-09, 1396/09/18**

Registration timing: **prospective**

Last update: **2017-12-09, 1396/09/18**

Update count: **0**

Registration date

2017-12-09, 1396/09/18

Registrant information

Name

Elnaz Hajhemati

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 5886

Email address

razmavarm1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-12-31, 1396/10/10

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of photodynamic therapy with light and laser on streptococcus mutans in patients undergoing fixed orthodontic treatment

Public title
The effectiveness of photodynamic therapy on streptococcus mutans

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Undergoing fixed orthodontic treatment Healthy teeth condition No oral lesions
Exclusion criteria:
Mass of gum Severe caries

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
A randomized based on random number table

Blinding (investigator's opinion)
Not blinded

Blinding description
In a single-blind study, the patients are not aware of the type of Streptococcus mutans 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
2015-05-15, 1394/02/25
Ethics committee reference number
IR.MUMS.SD.REC.1394.146

Health conditions studied

1

Description of health condition studied

orthodontic

ICD-10 code

Z46.5

ICD-10 code description

Fitting and adjustment of ileostomy and other intestinal appliances

Primary outcomes

1

Description

The Streptococcus mutans count

Timepoint

Before and 4 weeks after the intervention

Method of measurement

Microbial counting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group I: Who will receive chlorine-based photodynamic therapy with wavelength of 660 nm and red laser diodes power of 200 μ for 45 second once a week for 4 weeks.

Category

Prevention

2

Description

Intervention Group II: Who will be receive toluidine blue-mediated photodynamic therapy with wavelength of 480 nm and light blue LED power of 2000-4000 mw/cm 45 second once a week for 4 weeks.

Category

Prevention

3

Description

Intervention Group III: Who will receive photodynamic therapy using Emondo as photocatalytic material with wavelength of 810 nm and laser power of 200 μ for 45 second once a week for 4 weeks.

Category

Prevention

4

Description

Control group: Who does not receive photodynamic therapy

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Elnaze Hajhemati

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3883 2300

Email

elnazhematy@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, 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
Street

City

Mashhad

Province

Razavi Khorasan

Postal code

۳۴۵ - ۹۱۳۷۵

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

Vice Chancellor for Research, 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 Faculty of Dentistry

Full name of responsible person

Elnaze Hajhemati

Position

Orthodontic Residents

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Opposite Mellat Park, Vakilabad Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3883 2300

Fax

Email

elnazhematy@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad Faculty of Dentistry

Full name of responsible person

Elnaze Hajhemati

Position

Orthodontic Residents

Latest degree

Specialist
Other areas of specialty/work
Dentistry
Street address
Opposite Mellat Park, Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3883 2300
Fax
Email
elnazhematy@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad Faculty of Dentistry
Full name of responsible person
Elnaze Hajhemati
Position
Orthodontic Residents
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Opposite Mellat Park, Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3883 2300
Fax

Email
elnazhematy@yahoo.com
Web page address

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

Yes - There is a plan to make this available

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

Elnaz Hajhemati provides the analysis code to the applicants via email: elnazhematy@yahoo.com

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as an article six months.

Comments