Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Web page address

Person responsible for updating data

Contact

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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 a article six months.

Comments