

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### A comparison of effect of photodynamictherapy with LED and Calcium Hydroxide therapy on root canal disinfection in pasienst's treated teeth and periapical lesion

#### Protocol summary

##### Summary

Objectives: Comparison of antibacterial effect of intracanal calcium hydroxide and photodynamic therapy by LED against E.faecalis after retreatment in patients' teeth with periapical lesions Design, Setting and conduct: Study population involves 2 of 10 person group of patient presenting to endodontic department (just one center) with molars that their root canal therapies failed, and have periapical lesions (major eligibility criteria). Patients will be allocated to the groups according to computer generated random number table. After chemomechanical cleaning, blind practitioner carries out the first sampling by sterile rotary file. Then group 1 (n=10) goes under the photodynamic therapy (first intervention) and group 2, calcium Hydroxide therapy for 2 weeks (intervention 2). The second samples will be obtained from both groups. First and second samples cultured on specific culturing environment of E.faecalis and the results of colony counting reported as CFUs (primary outcome variables). If the result of each fist sample culturing be negative, the sample would be excluded (major exclusion criteria). Then the results will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092624206N1**  
Registration date: **2016-06-18, 1395/03/29**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-06-18, 1395/03/29

#### Registrant information

##### Name

Afsaneh Rahmati

##### Name of organization / entity

Shahid Beheshti university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Laser application in medical science research center, Shahid Beheshti University of Medical Science, Tehran, Iran

#### Expected recruitment start date

2016-05-04, 1395/02/15

#### Expected recruitment end date

2016-05-30, 1395/03/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

A comparison of effect of photodynamictherapy with LED and Calcium Hydroxide therapy on root canal disinfection in pasienst's treated teeth and periapical lesion

#### Public title

A comparison of effect of photodynamictherapy with LED and calcium hydroxide therapy on root canal disinfection

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: 1- Visible PA lesion must be presented  
2- No clinical symptoms 3- no systemic disease exclusion  
criteria: 1- negative culture of E.faecalis before PDT or  
Ca(OH)<sub>2</sub> therapy

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

allocation to groups according to computer generated  
random number table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of  
Medical Science, Laser Application in Medical Science

##### Street address

Shohadaye Tajrish hospital, Tajrish square

##### City

Tehran

##### Postal code

#### Approval date

2016-03-06, 1394/12/16

#### Ethics committee reference number

IR.SBMU.REC.1394.176

## Health conditions studied

### 1

#### Description of health condition studied

Root canal infection

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

CFU counting of E.faecalis

#### Timepoint

before and after treatments

#### Method of measurement

inspection with colony counter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: photodynamic therapy with LED  
FotOSan ( MDD, CMS Dental Denmark Korea) 200  
mW/cm<sup>2</sup> wave length: 630 nm for 60 s photosensitizer:  
toloeiden blue 15 µg/ml for 5 min

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: putting intracanal calcium  
hydroxide paste for 2 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endodontic department, school of dentistry, Shahid  
Beheshti University of Medical Science

##### Full name of responsible person

Mohammad Asnaashari

##### Street address

Faculty of dentistry, Shahid Beheshti University of  
Medical Science, Daneshjoo Boulevard, Evin

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Laser application in medical science research  
center, Shahid Beheshti University of Medical Science

##### Full name of responsible person

Mohammad Reza Razzaghi

##### Street address

Shohadaye Tajrish hospital,Tajrish square

**City**  
Tehran

**Grant name**  
-

**Grant code / Reference number**  
-

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Laser application in medical science research center,Shahid Beheshti University of Medical Science

**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**  
Shahid Beheshti University of Medical Science

**Full name of responsible person**  
Afsaneh Rahmati

**Position**  
Resident of Endodontics

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*