

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

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Iran (Islamic Republic of)

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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)₂ 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/cm² 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

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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
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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
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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