

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Determination of bacterial agents involved in root canal of patients with endodontic infection and evaluation of effect of photo-activated disinfection (PAD) on reduction of bacterial population

Protocol summary

Summary

The aim of this study is the determination of bacterial agents involved in endodontic infection by using Multiplex Real Time PCR on clinical specimens and culture before and after the effect of PAD. The confirmation of endodontic disease in the canine teeth of patient by dentist is inclusion criteria and having a sharp curve observed in X-rays in root canal is exclusion criteria. Sampling is done from the single-channel tooth pulp of 50 patients with endodontic infections. Following the identification of bacterial agents, the impact of indocyanine green is evaluated on expression of at least two virulence factors of resistant bacterial species to PAD by RT-PCR.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031321455N1**

Registration date: **2015-08-06, 1394/05/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-06, 1394/05/15

Registrant information

Name

Abbas Bahador

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Funding for the project is the responsibility of the School of Medicine, Tehran University of Medical Sciences.

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of bacterial agents involved in root canal of patients with endodontic infection and evaluation of effect of photo-activated disinfection (PAD) on reduction of bacterial population

Public title

Effect of laser on reduction of bacterial agents involved in root canal infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patient did not receive antibiotics for at least a month; The patient is not using immunosuppressive drugs; The patient has not systemic disease; The dentist is confirmed endodontic disease in his canine teeth (according to abscess, radiography and ...).
Exclusion criteria: The patient's age should not be less than 18 years (due to lack of complete form of APEX) and not be more than 50 years (due to necrotic pulp);

There is a sharp curve in root canal in radiography findings.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethical committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina Ave., Keshavarz Blvd, Tehran, Iran

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Tehran

Postal code

14167-53955

Approval date

2015-04-26, 1394/02/06

Ethics committee reference number

tums.rec 27681

Health conditions studied**1****Description of health condition studied**

Endodontic infection

ICD-10 code

XXII

ICD-10 code description

Codes for special purposes

Primary outcomes**1****Description**

Growth of bacteria

Timepoint

Before and after of interferer

Method of measurement

Culture

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Indocyanine green as photosensitizer with concentrations of 500 and 1000 ug/L

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dentistry College

Full name of responsible person

Dr. Nasim Chiniforush

Street address**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Unesian

Street address

Tehran University of Medical Sciences, Poursina Ave., Keshavarz Blvd, Tehran, Iran

City

Tehran

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 of Tehran University of Medical Sciences

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

School of Medicine, Tehran University of Medical Sciences

Full name of responsible person

Maryam Pourhajibagher

Position

PhD Student

Other areas of specialty/work

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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