

# 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)

###### Phone

+98 21 8895 5810

##### Email address

m-pourhajibagher@razi.tums.ac.ir

##### 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 used immunosuppressive drugs; The patient has not systemic disease; The dentist is confirmed endodontic disease in his canine teeth (according 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 be 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

**City**

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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Associate Professor

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Tehran University of Medical Sciences

**Full name of responsible person**

Samira Gharesi

**Position**

MS

**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*