

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of outcomes of single- versus multiple-visit in endodontically treated anterior and premolar teeth, using Cone-beam Computed Tomography

Protocol summary

Study aim

Comparison of outcomes of single- versus multiple-visit in endodontically treated anterior and premolar teeth, using Cone-beam Computed Tomography

Design

A randomized, double-blinded, phase III clinical trial outcome assessment

Settings and conduct

This study will be conducted at Dept. of Endodontics, Shahid Beheshti Dental School. Patients meeting the inclusion criteria will be randomly assigned to two groups after filling a written informed consent. CBCT image of the region of interest would be taken before any interventions. A similar standard treatment protocol will be performed in both groups, other than the placement of intra-canal calcium hydroxide in the two-visit group. The coronal restoration will be placed no later than one week. After one year another CBCT image will be taken and the reduction in periapical lesion volume will be measured and analyzed. The statistician and two calibrated clinicians who analyze the CBCT images will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with at least one maxillary/mandibular, anterior/premolar tooth with mature apex and no previous root canal therapy Necrotic pulp confirmed by cold and electric pulp tests Detectable periapical radiolucency in the periapical radiograph and the largest diameter within 2-5 millimeters Teeth without periodontal disease Sufficient coronal structure for proper isolation and direct restoration No history of antibiotic intake for the past one month Exclusion criteria: All patients with current or a history of systemic diseases interfering with tissue healing (diabetes mellitus, under radiotherapy, on bisphosphonates, immunocompromised)

Intervention groups

Intervention: Two-visit root canal treatment using calcium hydroxide as intra-canal medicament Control: Single-visit root canal treatment

Main outcome variables

Reduction in the volume of periapical lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190331043142N1**

Registration date: **2019-04-18, 1398/01/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Registrant information

Name

Mandana Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2205 6675

Email address

m.naseri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-08, 1398/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes of single- versus multiple-visit in endodontically treated anterior and premolar teeth, using Cone-beam Computed Tomography

Public title

Effect of the number of treatment visits on the outcome of root canal therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with at least one maxillary/mandibular, anterior/premolar tooth with mature apex and no previous root canal therapy Necrotic pulp confirmed by cold and electric pulp tests Detectable periapical radiolucency in the periapical radiograph and the largest diameter of the periapical radiolucency within 2-5 millimeters Teeth without periodontal disease Sufficient coronal structure for proper isolation and direct restoration No history of antibiotic intake for the past one month

Exclusion criteria:

All patients with current or a history of systemic diseases interfering with tissue healing (diabetes mellitus, patients under radiotherapy, use of bisphosphonates, immunocompromised patients)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization and specifically random allocation rule was utilized in order to make the sample size in both groups equal. The whole sample size had been determined in advance (n=30) and was divided equally between two groups. Fifteen cards coded 1 and 15 others cards coded 2 were placed in an opaque bowl. A person blinded to the study picked a card from this bowl for each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The clinician could not be blinded to the procedure. Two

calibrated clinicians other than the practitioner who performed the procedure would further analyze the size of the lesion in CBCT images. The statistician will be also blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti Univrsity of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Velenjak St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.SBMU.DRC.REC.1397.069

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

Chronic apical periodontitis

ICD-10 code

K04.5

ICD-10 code description

Chronic apical periodontitis of pulpal origin

2**Description of health condition studied**

Periapical abscess with sinus tract

ICD-10 code

K04.6

ICD-10 code description

Periapical abscess with sinus

3**Description of health condition studied**

Periapical abscess without sinus

ICD-10 code

ICD-10 code description

Periapical abscess without sinus

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

The volume of periapical lesions

Timepoint

Baseline, 1 year follow up

Method of measurement

Measurement of the volume of the lesion using Cone-beam Computed Tomography

Secondary outcomes

empty

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

Intervention group: Using calcium hydroxide as intra-canal medicament for 1 week and performing the root canal therapy in two visits.

Category

Treatment - Drugs

2**Description**

Control group: Performing the root canal treatment in a single visit with no calcium hydroxide dressing

Category

Treatment - Drugs

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

Dept. of Endodontics, Dental School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mandana Naseri

Street address

Dental School, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Evin, Shahid Chamran Highway

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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6th floor, Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Yemen St., Shahid Chamran Highway, Tehran, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mandana Naseri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Currently, we cannot publish individual patient data because of the need for further studies and analyses.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available