Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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+98 21 2205 6675
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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 University 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

K04.7

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

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

Contact

Name of organization / entity
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Full name of responsible person
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Atefeh Gohari

Position
Postgraduate student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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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