

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Antibacterial effect of sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder versus sodium hypochlorite 6% alone on the endodontic lesion in patients with apical periodontitis: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the antibacterial effect of sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder versus sodium hypochlorite 6% alone on endodontic lesion Design: a double blind, randomized clinical trial. Setting and conduct: The eligible patients with single-rooted tooth with pulp necrosis and apical periodontitis who will refer to Dentistry School during the study period will be enrolled into the trial. Inclusion criteria: (a) having single-rooted tooth with pulp necrosis and apical periodontitis; (b) having a negative response to pulp test; (c) presence of radiographic lesion. Exclusion criteria: (a) receiving antibiotic during the last three months; (b) extensive decay or fracture of the crown or root; (c) tooth with previous root canal repair; (d) teeth with probing more than 4 mm in depth. Intervention: Irrigation of root canal with 10 ml sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder. Control: Irrigation of root canal with 10 ml sodium hypochlorite 6%. Primary outcome: Evaluation of Enterococcus faecalis colonization 2 weeks after treatment using bacterial counts Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502169014N55**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

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Jalal Poorolajal

Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2014-09-13, 1393/06/22

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibacterial effect of sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder versus sodium hypochlorite 6% alone on the endodontic lesion in patients with apical periodontitis: a double blind randomized clinical trial

Public title

Antibacterial effect of sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder versus sodium hypochlorite 6% alone on the endodontic lesion in patients with apical periodontitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: (a) having single-rooted tooth with pulp necrosis and apical periodontitis; (b) having a negative response to pulp test; (c) presence of radiographic lesion. Exclusion criteria: (a) receiving antibiotic during the last three months; (b) extensive decay or fracture of the crown or root; (c) tooth with previous root canal repair; (d) teeth with probing more than 4 mm in depth.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: random assignment of the patients systematically one at a time to intervention and control groups. Blinding: Patients will not be aware of the type of treatment they receive. The examiner who will examine the patients is another person that will not be aware of the type of intervention. Therefore, the trial will be run as double blinded.

Secondary Ids

empty

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

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2015-02-15, 1393/11/26

Ethics committee reference number

P/16/35/9/5946

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

apical periodontitis

ICD-10 code

K04.4

ICD-10 code description

Acute apical periodontitis of pulpal origin

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

Evaluation of Enterococcus faecalis colonization

Timepoint

2 weeks after treatment

Method of measurement

using bacterial counts

Secondary outcomes**1****Description**

Nothing

Timepoint

Nothing

Method of measurement

Nothing

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

Irrigation of root canal with 10 ml sodium hypochlorite 6% plus chlorhexidine 0.2% and calcium hydroxide powder.

Category

Treatment - Drugs

2**Description**

Irrigation of root canal with 10 ml sodium hypochlorite 6%.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry School

Full name of responsible person

Dr Parastoo Ghahari

Street address

Dentistry School, Shahid Fahmideh Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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

Dentistry School

Full name of responsible person

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Position

Resident of Endodontic

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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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