

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Antibacterial power of different irrigation solutions (sodium hypochlorite, hypoclean, CHX, CHX pluse) in primary endodontic infection: clinical trial

Protocol summary

Summary

Objective: Determine the antibacterial effectiveness of root canal irrigator in primary endodontic infection
Design: Determine and comparison of the count of *Enterococcus faecalis* and *Fusobacterium nucleatum* before and after irrigation with sodium hypochlorite 5.25%, hypoclean, chlorhexidine 2% and chlorhexidine plus in primary endodontic infection. Setting and conduct: 40 consented patients who are referred to the endodontic department of Tehran university of medical sciences with primary endodontic infection in single rooted premolar will participate in this study. Patients are divided into 4 groups randomly and in each group one of the irrigators will be used. After sterilization, We'll sampling of intracanal before and after irrigation. The number of bacteria in all samples will be determined by use of molecular methods. Collected data will be analyzed by using statistical methods (T-test). Inclusion criteria: Premolar teeth with single root and the single canal; Necrotic teeth confirmed with no response to cold test; Tooth that is sensitive to percussion and palpation
Exclusion criteria: History of antibiotic therapy in last 3 months; Systemic disease; Tooth that is unable to isolate with rubber dam; Periodontal pocket more than 4 mm
Intervention: root canal irrigation by 5 milli litre of one of irrigators in each group (sodium hypochlorite 5.25% in first group, hypoclean in second group, chlorhexidine 2% in third group, chlorhexidine plus in fourth group) for 20 min during root canal therapy
Main outcome measures: the count of *Enterococcus faecalis* and *Fusobacterium nucleatum*

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111530899N1**

Registration date: **2017-02-08, 1395/11/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-08, 1395/11/20

Registrant information

Name

Sedigheh Khedmat

Name of organization / entity

Tehran University of Medical Sciences, Faculty of dentistry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2016-12-05, 1395/09/15

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibacterial power of different irrigation solutions (sodium hypochlorite, hypoclean, CHX, CHX pluse) in primary endodontic infection: clinical trial

Public title

Comparison of Antibacterial effect of intra canal irrigators

(sodium hypochlorite, hypoclean, CHX and CHX pluse) in teeth with primary endodontic infection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Premolar teeth with single root and single canal; Necrotic teeth confirmed with no response to cold test; Tooth that is sensitive to percussion and palpation Exclusion criteria: History of antibiotic therapy in last 3 months; Systemic disease; Tooth that is unable to isolation with rubber dam; Periodontal pocket more than 4 mm

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomized with close packets

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran university of medical science

City

Tehran

Postal code

Approval date

2016-12-14, 1395/09/24

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1232

Health conditions studied

1

Description of health condition studied

Primary endodontic infection

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes

1

Description

Number of enterococcus faecalis

Timepoint

Before and after canal irrigation within 20 min

Method of measurement

Real time PCR

2

Description

Number of fusobacterium nucleatum

Timepoint

Before and after canal irrigation within 20 min

Method of measurement

Realtime PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: root canal irrigation by 5 milliliter sodium hypochlorite 5.25% (ERKAMED. MEDICAL COMPANY) for 20 min during root canal therapy

Category

Other

2

Description

Intervention group: root canal irrigation with 5 milliliter chlorhexidine 2% (ERKAMED. MEDICAL COMPANY) for 20 min during root canal therapy

Category

Other

3

Description

Intervention group: root canal irrigation with 5 milliliter Hypoclean (Ogna Laboratori Farmaceutici, Milano, Italy) for 20 min during root canal therapy

Category

Other

4

Description

Intervention group: root canal irrigation with 5 milliliter CHX-Plus (Vista Dental Products, Racine, WI) for 20 min during root canal therapy

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic department, Faculty of dentistry, Tehran university of medical science

Full name of responsible person

Nooshin Fakhari

Street address

Tehran dental school, North kargar street, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Mohammad sadegh Ahmadakhondi

Street address

Dental school, North Kargar street, Tehran

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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

Tehran University of Medical Sciences Faculty of Dentistry

Full name of responsible person

Nooshin Fakhari

Position

Resident of endodontic department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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