Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of intracanal drugs on calcium hydroxide blend with nano silver particles and calcium hydroxide blend and normal saline on pain relief between root canal therapy in patients with symptomatic apical periodontitis

Protocol summary

Study aim
Comparison of the effect of calcium hydroxide with nano-silver particles and calcium hydroxide and normal saline as intracanal medications on pain between sessions in premolar teeth with symptomatic apical periodontitis.

Design
In this single-blind randomized clinical trial study, 30 patients with healthy systemic conditions and premolar teeth with pulp and periapical conditions requiring root canal treatment with symptomatic apical periodontitis were selected. Patients were divided into 3 parallel 10-person groups including study and control groups, and patients in each group received different root canal medications. To choose intracanal medication 10 numbers of each intracanal medications were written on identical pieces of paper then asked the assistant to one sheet of paper for each patient .

Settings and conduct
Study Area: Dental Clinic, Faculty of Dentistry, Army University of Medical Sciences. pain between the root canal treatment sessions was measured using visual analogue scale (VAS) and its relationship with intracanal medications was evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criterion: patient with premolar tooth with closed apex and symptomatic apical periodontitis. Non-inclusion criteria: pregnancy; Not repairable teeth; presence of any resorption; systemic disease; history of chronic use of Analgesics, drugs or alcohol; using antibiotics and pretreatment analgesics.

Intervention groups
Intervention group 1: mixture of calcium hydroxide with silver nano particles. Intervention group 2: Mixture of calcium hydroxide with normal saline. Control group: Sterile dry cotton pellet. Standard root canal treatment was performed for patients in two sessions and at the end of the first session, the intracanal medications were used for patients in the study groups.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190323043102N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **retrospective**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date
2020-03-14, 1398/12/24

Registrant information

Name
Mohsen Mortezaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-01, 1398/04/10

Expected recruitment end date

2019-10-03, 1398/07/11

Actual recruitment start date

2019-07-01, 1398/04/10

Actual recruitment end date

2019-12-30, 1398/10/09

Trial completion date

2019-12-30, 1398/10/09

Scientific title

Comparison of the effect of intracanal drugs on calcium hydroxide blend with nano silver particles and calcium hydroxide blend and normal saline on pain relief between root canal therapy in patients with symptomatic apical periodontitis

Public title

Effect of nano silver particles on pain control between root canal therapy sessions in premolar teeth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient seeking root canal treatment closed apex

Exclusion criteria:

Systemic disease tooth with internal or external resorption Use of antibiotics and analgesics before treatment pregnancy Non-repairable teeth A history of chronic use of analgesics, narcotic or alcohol

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were categorized by an assistant using random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

number 1 was assigned to calcium hydroxide with nano silver particles , number 2 was assigned to calcium hydroxide , number 3 was assigned to sterile dry cotton pellet. Then, on behalf of the intracanal drug type, 10 numbers of each intracanal medication were written on identical so that the numbers could not be identified. The papers were poured into a box and we asked the ward assistant to remove one sheet of paper for each patient and enter it into the file. The patient and data analyzer were unaware of the root canal drug type and after data collection, the number assigned to each intracanal medication was reported to the data analyzer instead of the type of intracanal medication.

Placebo

Used

Assignment

Parallel

Other design features

Silver nano particles are a new material in dentistry and most of the studies on this material are about its antibacterial properties. Microorganisms are the main cause of pain between root canal treatment sessions with apical periodontitis. So we decided to design a study about the relation of the pain between root canal therapy sessions and nano silver particles.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemadzade avenue., West Fatemi boulevard, Tehran

City

Tehran

Province

Tehran

Postal code

6523545522

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

IR.AJAUMS.REC.1397.082

Health conditions studied

1

Description of health condition studied

Pain between root canal treatment sessions

ICD-10 code

K04.4

ICD-10 code description

Acute apical periodontitis of pulpal origin

Primary outcomes

1

Description

Post-treatment pain above 3

Timepoint

between two root canal sessions at 6, 12 , 24 and 48 hours after first session (2 session root canal with intracanal medication)

Method of measurement
Visual analog scale (VAS): patients are asked to mark the pain level at 6, 12 , 24 and 48 hours after first session of their treatment then the 10 cm line of each period was measured from left(no pain) in millimeter.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In patient's premolar teeth with symptomatic apical periodontitis, calcium hydroxide with silver nano particles was used as intracanal medication one time between root canal therapy sessions at the end of the first treatment session after cleaning and shaping of root canal system for 4 days.
Category
Prevention

2

Description
Intervention group 2: In patient's premolar teeth with symptomatic apical periodontitis, calcium hydroxide with normal saline was used as intracanal medication one time between root canal therapy sessions at the end of the first treatment session after cleaning and shaping of root canal system for 4 days.
Category
Prevention

3

Description
Control group: In patient's premolar teeth with symptomatic apical periodontitis, sterile dry cotton pellet was used as placebo medication one time between root canal therapy sessions at the end of the first treatment session after cleaning and shaping of root canal system for 4 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry college of AJA University of Medical Science
Full name of responsible person
Mohsen Mortezaei
Street address
Misagh complex, East 13 alley, Sabari street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
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http://www.ajaums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Mohsen Mortezaei
Position
student
Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Patient record, file summary, visual analogue scale (VAS) form, and 5 periapical graphs of patients are available which can be published if necessary after deleting patients' names and telephone numbers.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Those who are researching silver nanoparticles Comparison of pain levels between sessions in the upper and lower jaw Comparison of pain between sessions between men and women

From where data/document is obtainable

mmortezaei7777@gmail.com Department of Endodontics, Faculty of Dentistry, Army University of Medical Sciences

What processes are involved for a request to access data/document

The reason for the data request should be verified by the endodontic department.

Comments