Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of the Efficacy of Intracanal Medicaments on Tooth Root Canal Treatment Pain Management

Protocol summary

Study aim
Assessment and comparison of pain relief effect of three intracanal medicament after cleaning and shaping of tooth root canal.

Design
Three blinded randomized trial (randomized by random number table) which will conduct to compare pain relieving effect of three root canal medicaments.

Settings and conduct
Patients referring to office of the conductor dentist of the study are the target group. Patient, dentist and statistical analyzer will be blinded and drugs will be prepared and given to the dentist by the dental assistant

Participants/Inclusion and exclusion criteria
inclusion criteria: without any systemic diseases, molar or premolar tooth with necrotic pulp, permanent and closed apex tooth, tooth shouldn't have any kind of resorption and patient should not use any NSAIDS in last three hours before treatment. exclusion criteria: patient won't come for the following treatment appointment, patient doesn't prefer to collaborate and don't complete the pain in the charts by the patient.

Intervention groups
this study includes three case groups: treatment will done by mixture of "calcium hydroxide and %0/9 normal saline", "calcium hydroxide and %2 Chlorhexidine" and "calcium hydroxide and dexamethasone (8mg/2cc)". after cleaning and shaping one of these mentioned medicament will apply in root canal for comparison of their pain relieving effect.

Main outcome variables
inter appointments pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180521039766N1**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-29, 1401/11/09**
Update count: **1**

Registration date
2018-06-25, 1397/04/04

Registrant information

Name
Arash Ghanbarzadegan

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the Efficacy of Intracanal Medicaments on Tooth Root Canal Treatment Pain Management

Public title
Intracanal Medicaments and Root Canal Treatment Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

without any systemic diseases molar or premolar tooth with necrotic pulp permanent and closed apex tooth tooth shouldn't have any kind of resorption patient should not use any NSAIDS in last three hours before treatment

Exclusion criteria:

patient won't come for the following treatment appointment patient doesn't prefer to collaborate don't complete the pain in the charts by the patient

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

patient will be select by random number table.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patient, dentist and statistical analyzer will be blinded and drugs will be prepared and given to the dentist by the dental assistant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Aja University of Medical Sciences

Street address

Etemadzadeh St., West Fatemi St.

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Province

Tehran

Postal code

1411718541

Approval date

2018-06-03, 1397/03/13

Ethics committee reference number

IR.AJAUMS.REC.1397.005

Health conditions studied

1

Description of health condition studied

inter appointments pain after cleaning and shaping of root canal

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

inter appointments pain after cleaning and shaping of tooth root canal

Timepoint

4 hours after treatment, the first day, the second day, the third day and the fourth day.

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: treated by mixture of calcium hydroxide and %0/9 normal saline.

Category

Treatment - Drugs

2

Description

Intervention group: treated by mixture of calcium hydroxide and %2 Chlorhexidine.

Category

Treatment - Drugs

3

Description

Intervention group: treated by mixture of calcium hydroxide and dexamethasone (8mg/2cc).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali- Asr clinic

Full name of responsible person
Arash Ghanbarzadegan

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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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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
Arash Ghanbarzadegan

Position
Researcher Dentist

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable

Trial results

Please tick if results have been published
Yes
Summary result posting date
2023-01-29, 1401/11/09
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2019-01-20, 1397/10/30
Abstract of published paper
Abstract Introduction: After treating the tooth root canal, pain is one of the problems that many patients are facing. In order to reduce pain, and regarding the advice of treating necrotic teeth during several sessions, intra-canal medicaments can be used between sessions. The purpose of this study is to compare pain relieving effect of calcium hydroxide combined with three solutions of normal saline, chlorhexidine 2% and dexamethasone. Materials and methods: This triple blind randomized clinical trial was performed on 90 necrotic molars and premolars. The patients were classified in three medicaments' groups including mixture of calcium hydroxide and normal saline (G1), chlorhexidine 2% (G2) or dexamethasone (G3) that were placed in the canal during the first treatment session. The patients were provided with a Heft-Parker Visual Analog Scale form to record their pain in different intervals of 4, 24, 48, 72 and 96 h after cleaning and shaping the root canal. Data analysis was carried out using the Chi-Square, one-way ANOVA and Repeated Measure tests. Results: No significant difference was observed in the mean pain of the groups after 4 h (P>0.05). However, a significant difference was found between G1 and G3 in the mean pain from day 1 to 72 h after treatment. The mean pain was less in dexamethasone (G3) group (P<0.05), but the difference was not statistically significant at 96 h after treatment (P>0.05). No significant difference was found between "G2-G1" and "G2-G3" groups at different time intervals (P>0.05). Conclusion: The mixture of calcium hydroxide and dexamethasone compared to calcium hydroxide and normal saline in short and medium time had a significant effect on reducing pain after cleaning and shaping the root canal. It seems that the mixture of calcium hydroxide and dexamethasone can be considered as an effective medicament on reducing pain during root canal treatment sessions.