Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of irrigation with two concentration of sodium hypochlorite on postoperative pain following single-visit endodontic treatment: A triple blinded randomized clinical trial

Protocol summary

Summary

Aim: A comparison of two different concentrations of NaOCl on pain following single-visit root canal treatment. Methods: This study will be performed as a randomized triple-blinded clinical trial on 100 patients. The patients will be randomly allocated in two groups of 50 each and their root canals will be irrigated with either 5.25 or 2.5% of sodium hypochlorite. Inclusion criteria:No systemic disease, first and second mandibular molar with irreversible pulpitis, normal preapical radiography, mild sensitivity to percussion, no or mild pretreatment pain, having no medication at least 6 hours before the treatment visit, at least 18 years, no allergic reaction to the lidocaine with epinephrine 1:80000, gelofen, and sodium hypochlorite. Exclusion criteria: Pregnancy and lactation, severe periodontal diseases, over instrumentation or overfilling, teeth that cannot be isolated, root canal calcification, root resorption, and the teeth that cannot be restored. Root canals will be prepared in crown-down manner and RaCe rotary instruments. At the same visit the root canals will be obturated with cold lateral condensation technique using gutta-percha and AH26 root canal sealer. At the end of treatment visit, each patient will receive one cap of Gelofen (400 mg). The patients will be given two forms. A visual analogue scale form that records the they rate the severity of their pain during 7 days period following the treatment. The other form is pertaining to analgesic consumption. Statistical analysis will be performed by someone else using who will be unaware of the intervention.

General information

Acronym

Hypochlorite

IRCT registration information

IRCT registration number: **IRCT201601202016N6**
Registration date: **2016-01-24, 1394/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

Name

Masoud Parirokh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences

Expected recruitment start date

2016-01-15, 1394/10/25

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of irrigation with two concentration of sodium hypochlorite on postoperative pain following single-visit endodontic treatment: A triple blinded randomized clinical trial

Public title
Effect of concentration of irrigants on endodontic postoperative pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: no systemic disease; first and second mandibular molar with irreversible pulpitis; normal preapical radiography; mild sensitivity to percussion; no or mild pretreatment pain; having no medication at least 6 hours before the treatment visit; age at least 18 years old; no allergic reaction to the lidocaine with epinephrine 1:80000, gelofen, and sodium hypochlorite. Exclusion criteria: pregnancy and lactation; severe periodontal diseases; over instrumentation or overfilling; teeth that cannot be isolated; root canal calcification; root resorption; and the teeth that cannot be restored.
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Kerman University of Medical Sciences
Street address
Vice Chancellor of Research and Technology, Tahmasbabad Cross road, Kerman, Iran.
City
Kerman
Postal code
Approval date
2015-12-22, 1394/10/01
Ethics committee reference number
IR.KMU.REC.1394.293

Health conditions studied

1

Description of health condition studied
Irreversible Pulpitis
ICD-10 code
K04.0
ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Postoperative pain
Timepoint
Six, 12, 24, 48, 72 hours and 4, 5, 6, 7 days following the treatment
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description
Analgesic consumption
Timepoint
6, 12, 24, 48, 72 hours and 4, 5, 6, 7 days following the treatment
Method of measurement
Using a specific form

Intervention groups

1

Description
Intervention: 2.5% sodium hypochlorite will be used for irrigation during root canal preparation. Between instrumentation with each file to the next instrument, the root canals will be rinsed with 2mL of either of the irrigants. The needle will penetrate the root canals 2mm shorter than the working length.
Category
Treatment - Other

2

Description
Control: 5.25% sodium hypochlorite will be used for irrigation during root canal preparation. Between instrumentation with each file to the next instrument, the root canals will be rinsed with 2mL of either of the

irrigants. The needle will penetrate the root canal 2mm shorter than the working length.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endodontic Department, Kerman Dental School

Full name of responsible person
Masoud Parirokh

Street address
School of Dentistry, Shafa street

City
Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology

Full name of responsible person
Dr. Abbas Pardakhti

Street address
Tahmasbabad cross road, Vice Chancellor for Research and Technology building

City
Kerman

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 and Technology

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
Endodontology Research Center

Full name of responsible person
Dr. Arash Shahravan

Position
Dean of the center

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Full Professor

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Person responsible for updating data

Contact

Name of organization / entity
Kerman School of Dentistry

Full name of responsible person
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Position
Postgraduate student

Other areas of specialty/work

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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