

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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Kerman School of Dentistry

Full name of responsible person

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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