

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+98 34 1245 7931

###### Email address

m\_parirokh@kmu.ac.ir

##### 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****Street address**

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**Full name of responsible person**

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**Position**

Full Professor

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Kerman School of Dentistry

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Postgraduate student

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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*