

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

**Investigating the effect of dexamethasone as the final rinse inside the root canal compared to infiltration injection after the end of treatment in reducing pain after root canal treatment in patients with irreversible pulpitis.**

### Protocol summary

#### Study aim

Investigating the effect of dexamethasone as the final intra-canal rinse compared to infiltration injection after the end of treatment in reducing pain after root canal treatment in patients with irreversible pulpitis.

#### Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, on 96 patients. Randomization was done using the free database "https://www.sealedenvelope.com/" with Seed=127686074750462.

#### Settings and conduct

1- Place of study: endodontics department, dental clinic, Bushehr University of Medical Sciences 2- Study population: 96 referring patients who need one-session root canal treatment in their molar teeth, 3- Blinding: blinding will be performed on both the patient and the evaluator.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 years and older; diagnosis of symptomatic or asymptomatic irreversible pulpitis; absence of diabetes and cardiovascular diseases and allergic problems; willingness to cooperate; The possibility of one-session treatment; the possibility of achieving patency in all channels in radiography; the absence of periodontal problems. Exclusion criteria: the possibility of treatment complexity and prolonging the treatment time for more than 2 hours in radiography; history of gastric ulcer or gastrointestinal bleeding; history Hypersensitivity to NSAIDs or corticosteroids; risk of kidney damage.

#### Intervention groups

Intervention group 1: Dexamethasone infiltration near the tooth. Intervention group 2: Final rinsing of the canal with dexamethasone. Control group: no use of dexamethasone.

#### Main outcome variables

Average pain intensity

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20240109060657N1**

Registration date: **2024-02-12, 1402/11/23**

Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**

Update count: **0**

#### Registration date

2024-02-12, 1402/11/23

#### Registrant information

##### Name

mina seyed habashi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3332 2206

##### Email address

msarлак269@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2024-02-14, 1402/11/25

#### Expected recruitment end date

2024-02-24, 1402/12/05

#### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of dexamethasone as the final rinse inside the root canal compared to infiltration injection after the end of treatment in reducing pain after root canal treatment in patients with irreversible pulpitis.

**Public title**  
The effect of two methods of using dexamethasone in reducing pain after root canal treatment

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male and female patients Age over 18 years old Vital pulp with a diagnosis of symptomatic or asymptomatic pulpitis None of systemic diabetes and cardiovascular diseases and allergic problems Willingness to cooperate One-session root canal treatment The possibility of achieving patency in all canals in preoperative radiography Absence of periodontal problems  
**Exclusion criteria:**  
The complexity of the treatment and the possibility of prolonging the treatment time for more than 2 hours, which can be estimated from the patient's radiograph before starting the treatment. History of gastric ulcer or gastrointestinal bleeding History of allergy to NSAIDs or corticosteroids Risk of renal failure or renal damage

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **96**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are assigned to three treatment groups A, B, C using the method of random blocks (Balance block randomization), the size of each block is 6 and the total number of blocks is 16 as described in the attached table. Randomization was done using the free database "https://www.sealedenvelope.com/" with Seed=127686074750462. Therefore, in a randomized controlled clinical trial study, 32 patients in each group included local injection of dexamethasone (group A), final washing inside the canal with dexamethasone (group B) and no use of dexamethasone (group C) in reducing pain after molar root treatment. was included in the study in parallel.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**  
In this research, the patients are unaware of the intervention group in which they are placed. Root canal treatment in patients is performed by the therapist (root canal treatment specialist) and the evaluation is done by the student who is unaware of the type of treatment intervention.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics committee of Bushehr University of Medical Sciences

**Street address**  
Moallem blvd

**City**  
Bushehr

**Province**  
Boushehr

**Postal code**  
7514633341

**Approval date**  
2023-08-26, 1402/06/04

**Ethics committee reference number**  
IR.BPUMS.REC.1402.117

## 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**  
Average pain intensity

**Timepoint**  
in the times before intervention, 3 hours after treatment, 6 hours, 12 hours, 24 hours after treatment

**Method of measurement**  
NPRS ( Numeric Pain Rating Scale)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: dexamethasone infiltration injection; After the end of the root treatment, a carpool (2 ml) of dexamethasone containing 8 mg of dexamethasone phosphate (as disodium salt) from Darou pakhsh company is infiltrated on the buccal side of the tooth.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: final washing inside the canal with dexamethasone; After the preparation of the root canal and before filling the canal, the canal is washed with dexamethasone from Darou Pakhsh Company, and then the canal is dried and obturated.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: not using dexamethasone; The patient does not receive any intervention with dexamethasone during root canal treatment.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental Clinic of Bushehr University of Medical Sciences

##### Full name of responsible person

مینا سید حبشی

##### Street address

Moallem Blvd

##### City

Bushehr

##### Province

Boushehr

##### Postal code

7514633341

##### Phone

+98 77 3332 2081

##### Email

mina.s.habashi.64@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Boushehr University of Medical Sciences

##### Full name of responsible person

Akram Farhadi

##### Street address

Moallem Blvd

##### City

Bushehr

##### Province

Boushehr

##### Postal code

7514633341

##### Phone

+98 77 3345 0178

##### Email

ris@bpums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

##### Full name of responsible person

mina seyed habashi

##### Position

associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mina Seyed Habashi

**Position**

associate professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Mina Seyed Habashi

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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**Province**

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**Email**

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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**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Average amount of pain after treatment recorded by patients in all three groups and analysis of their results

**When the data will become available and for how long**

Beginning of the access period from 2024 to 2027

**To whom data/document is available**

The general public

**Under which criteria data/document could be used**

There are no special conditions.

**From where data/document is obtainable**

Mohammad Sarlak Email: msarlak269@gmail.com

Phone: 09184900295

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

Send a request to a phone number or email

**Comments**