Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 77 3332 2206

Email address
msarlak269@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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
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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
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
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mina seyed habashi
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
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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