

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison the effect of infiltration injection of dexamethasone and methylprednisolone on post endodontic pain in molars with necrosis pulp

Protocol summary

Study aim

Comparison the effect of infiltration injection of dexamethasone and methylprednisolone on post endodontic pain in molars with necrosis pulp

Design

Clinical trial without control group, double blind, Simple random allocation: The computer selects random numbers between 0 and 1 if the random number is <0.5 , one goes to group A, and if the random number is >0.5 , then the individual goes to group B. Sample size is 80 people. The trial phase is 2-3

Settings and conduct

This study is done at Yasuj Dental School. After anesthetic injection, one of the drugs Dexamethasone or methylprednisolone becomes injected, and 6, 12, 24 and 48 hours after the root canal therapy, pain is measured. blindness is performed using the medication sticker, both the patient and the dentist will be unaware of the content of the medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who need endodontic treatment for high and low molar teeth; being at the age of 18-60 years; patients with ASA 1 or 2 ; Teeth do not have any periapical lesions. Non Inclusion criteria: Patients who have received anti-inflammatory or analgesic medications within the last 8 hours; requiring antibiotic prophylaxis; Having systemic disease which are contraindicated with endodontic treatment; being pregnant or lactating.

Intervention groups

Intervention group 1: injection of dexamethasone (1ml) in buccal vestibule after anesthesia. Intervention group 2: injection of methylprednisolone (1ml) in buccal vestibule after anesthesia.

Main outcome variables

pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180104038222N1**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **prospective**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Sheyda Yeganegiasl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7286

Email address

sheyda94yeganegi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of infiltration injection of dexamethasone and methylprednisolone on post endodontic pain in molars with necrosis pulp

Public title
The effect of dexamethasone and methylprednisolone on post endodontic pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Required endodontic treatment in upper or lower molar teeth between 18 and 60 years of age Patients who are in healthy condition ASA 1 or 2 No periapical pathosis
Exclusion criteria:
 Patients who have received anti-inflammatory or analgesic drugs within last 8 hours Have a periodontal abscess or acute endodontic disease or any periodontal disease They need antibiotic prophylaxis Pregnant or lactating Have mental disabilities Have systemic disease which are contraindicated with endodontic treatment Have an acute infection Sensitivity to Dexamethasone and Methyl Prednisolone

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random allocation using random allocation software: The computer selects random numbers between 0 and 1. If the random number is <0.5, one goes to group A, and if the random number is > 0.5, then the individual goes to group B .

Blinding (investigator's opinion)
Double blinded

Blinding description
Blindness is done using the medication sticker, and both the patient and the dentist do not know the medication content.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasouj University of Medical Sciences

Street address

Shahid Motahari blvd

City

Yasouj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2017-12-15, 1396/09/24

Ethics committee reference number

IR.YUMS.REC.1396.136

Health conditions studied

1

Description of health condition studied

Post treatment endodontic pain

ICD-10 code

K08

ICD-10 code description

Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description

Post treatment endodontic pain intensity

Timepoint

level of pain before root canal treatment and after 6,12, 24 and 48 hours

Method of measurement

Heft-parker visual analoug scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Injection of 4 mg per cc dexamethasone in buccal vestibule after anesthetic injection. The drug is made in Iran and from the Alborz Pharmaceuticals Company with the chemical composition of C22H29FO5. The half-life of the drug is 36-54 hours. The severity of pain is recorded at 6, 12, 24, and 48 hours after treatment.

Category

Treatment - Drugs

2

Description

Intervention group 2: injection of 40 mg per cc of methylprednisolone in buccal vestibule after anesthetic injection. The drug is made in Iran and from Caspian Supply Company with chemical composition of C22H30O5. The half-life of the drug is 18-26 hours. The severity of pain is recorded at 6, 12, 24 and 48 hours after treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic affiliated by Yasouj University of Medical Sciences

Full name of responsible person

Mohammad Karim Layeghnejad

Street address

Dental clinic, Shohadaye Haft Ave.

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Email

Mohammad.layegh@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Mohammad karim Layegh Nejad

Street address

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Postal code

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Mohammad.layegh@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Sheyda Yeganegi Asl

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No. 8, 4th alley, Ayatollah Kashani Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sheyda Yeganegi Asl

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available