

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparative evaluation of the effect of topically applied Dentol drop and placebo on success of local anesthesia in mandibular molar teeth with irreversible pulpitis

Protocol summary

Summary

The purpose of this randomized, double blind clinical trial study is the evaluation of the effect of topically applied Dentol drop on success of local anesthesia in mandibular molar teeth with irreversible pulpitis. Eighty eight patients diagnosed with irreversible pulpitis of a mandibular molar tooth that are came to the personal office for root treatment and have below qualifications participate in this study: patients who are older than eighteen and have no systemic disease and patients diagnosed with irreversible pulpitis of a mandibular molar tooth with a deep caries cavity. Patients who have a mandibular molar tooth diagnosed with necrosis and PDL widening in radiographic view, exclude from the study. Patients are randomly divided into the intervention and control groups using sealed envelopes. Fifteen minutes after mandibular block injection when patients report lip numbness, in one group Dentol drop is applied into the caries cavity by using a piece of cotton for ten minutes and in the other group distilled water is applied into the caries cavity as a placebo, by using a piece of cotton for ten minutes and then access cavity preparation will be started. Before mandibular block injection, fifteen minutes after mandibular block injection and before applying Dentol drop and distilled water into the caries cavity and ten minutes after applying Dentol drop and distilled water, the teeth are tested with refrigerant spray, in this step and during access cavity preparation when the bur is entered in dentin and when the pulp is exposed and when initial file is inserted into the root canals, the patients rate their pain by using a Visual Analog Scale. Finally, the success of anesthesia will be compared with each other in these two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110617880N5**

Registration date: **2017-02-06, 1395/11/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

Name

Roohollah Sharifi

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Kermanshah University Of Medical Sciences

Expected recruitment start date

2016-09-29, 1395/07/08

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effect of topically applied Dentol drop and placebo on success of local anesthesia in mandibular molar teeth with irreversible pulpitis

Public title

Efficacy of Dentol drop on success of tooth anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with no systemic disease; patients with mandibular molar teeth with irreversible pulpitis and a deep caries cavity; patients who can read and understand visual analog scale Exclusion criteria: patients with systemic disease and mental retardation patients younger than 18; pregnant and lactating women; teeth with pulp necrosis; patients who have used Dentol drop before treatment

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomized using sealed envelopes

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti Boulevard, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2016-09-28, 1395/07/07

Ethics committee reference number

KUMS.REC.1395.372

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**

Pain rate

Timepoint

Before mandibular block injection, Fifteen minutes after mandibular block injection and before applying Dentol drop and placebo into the caries cavity, Ten minutes after applying Dentol drop and placebo into the caries cavity, During preparation of access cavity when bur is entered the dentin, Dental pulp exposure, When the initial file inserts into the root canals

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group : Applying Dentol drop into the caries cavity by using a piece of cotton, Fifteen minutes after mandibular block injection and when the patients report lip numbness

Category

Treatment - Drugs

2**Description**

Control Group : Applying distilled water as a placebo into the caries cavity by using a piece of cotton, Fifteen minutes after mandibular block injection and when the patients report lip numbness

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of endodontics, Kermanshah University of Medical Sciences, School of Dentistry

Full name of responsible person

Dr. Roohollah Sharifi

Street address

Opposite of the Post office, Shora street, Shariati street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Kourosh Hamzeei

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Building No.2, Shahid Beheshti Boulevard, Vice Chancellor for Research, Kermanshah 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

Ethics Committee of Kermanshah University of Medical Sciences

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**

Kermanshah Dentistry School

Full name of responsible person

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Position

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Web page address

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