Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Comparative evaluation of the effect of topically applicated 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 applicated 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 envelops. 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
Country
Iran (Islamic Republic of)
Phone
+98 83 1722 2400
Email address
r.sharifi@kums.ac.ir

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 applicated 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 envelops

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sceinces
Street address
Building No.2, Shahid Beheshti Boulverd, 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 in 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 ofiice, Shora street, Shariati street

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ethics Committee of Kermanshah University of Medical Sciences

Full name of responsible person
Kourosh Hamzeei

Street address
Building No.2, Shahid Beheshti Boulverd, Vice Chancellor for Research, Kermafnshah University of Medical Sciences

City
Kermanshah

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
Dr. Roohollah Sharifi

Position
assistant professor

Other areas of specialty/work

Street address
Opossite the post office, Shora street, Shariati street

City
Kermanshah

Postal code
6713954658

Phone
+98 83 3723 7434

Fax

Email
r.sharifi@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah Dentistry School

Full name of responsible person
Dr. Roohollah Sharifi

Position
PHD

Other areas of specialty/work

Street address
Opossite the post office, Shora street, Shariati street

City
Kermanshah

Postal code

Phone
+98 83 3723 7434

Fax

Email
r.sharifi@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah Dentistry School

Full name of responsible person
Dr. Roohollah Sharifi

Position
Assistant Professor

Other areas of specialty/work

Street address
Opossite the post office, Shora street, Shariati street

City
Kermanshah

Postal code

Phone
+98 83 3723 7434

Fax

Email
r.sharifi@kums.ac.ir

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