Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of premedication with two drugs:oral Dextrometorphan and Ibuprofen on post root canal therapy pain in pateints with irriversible pulpitis in first mandibular molar.

Protocol summary

Summary

None steroidal anti-inflammatory drugs are the most commonly used analgesics with gastrointestinal side effects. The researchers are looking for alternative drugs with fewer side effects. This study aims to determine the effect of the oral Dextromethorphan (N-methyl-D-aspartate receptor antagonist) in comparison with Ibuprofen in pain after root canal therapy. This double-blind randomized clinical trial has placebo controlled. Research will be done on healthy patients need endodontic treatment of first lower molar with irreversible pulpitis, spontaneous pain and no apical lesions. Patients are excluded with necrotic tooth or inability to complete treatment in one visit.45 patients participate in this research. Randomly, patients are given a single dose of dextromethorphan, ibuprofen, or placebo an hour before the beginning of treatment and receiving anesthesia. Then root canal treatment is completed in one visit. Pain intensity is evaluated by a questionnaire according to the visual analogue scaling method at intervals of 2, 4, 8 and 12 hours after root canal treatment. The patients are asked to mark in the questionnaire if they take analgesics, ultimately these patients will be excluded. Questionnaires are collected in the crown restoration appointment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070228732N1**
Registration date: **2017-04-23, 1396/02/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-23, 1396/02/03

Registrant information

Name
Elmira Ahmadpour
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Isfahan Islamic Azad University Khorasgan branch

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of premedication with two drugs:oral Dextrometorphan and Ibuprofen on post root canal therapy pain in pateints with irriversible pulpitis in first mandibular molar.

Public title

The effect of premedication on post root canal therpy pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients with systemic health; suffered from irreversible pulpitis with spontaneous pain in the lower first molar; The patient didn't get analgesics 12 hours before the treatment ; Have only one painful tooth; Tooth without radiographic radiolucency; viewing vital pulp during access cavity preparation; Possibility of completing treatment in one visit. Exclusion criteria:Patients with systemic disease; patients who took analgesics 12 hours before the treatment; Teeth with apical radiographic radiolucency ;necrotic tooth; Not possible to complete the treatment in one visit.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Treatment is done by two Endodontics with crown down technique.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Islamic Azad University khorasgan branch

Street address

Islamic Azad University, khorasgan, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2017-03-09, 1395/12/19

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1395.13

Health conditions studied

1

Description of health condition studied

Toothache

ICD-10 code

G50-10

ICD-10 code description

Atypical facial pain

Primary outcomes

1

Description

pain after root canal therapy

Timepoint

2,4,6,8 hours after intervention.

Method of measurement

Visual Analog Scaling

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

intervention:oral Dextrometorphan,30 mgr,single dose,1 hour before root canal therapy.

Category

Treatment - Drugs

2

Description

intervention:oral Ibuprofen,600 mgr,single dose,one hour before root canal therapy.

Category

Treatment - Drugs

3

Description

control:placebo,single dose,one hour before root canal therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic in Isfahan

Full name of responsible person

Dr Maryam Zare Jahromi
Street address
no 601, 6th floor, Faraz building, In front of Shariati clinic, Shariati street, Isfahan
City
Isfahan

2

Recruitment center
Name of recruitment center
private clinic in Isfahan
Full name of responsible person
Dr kamal Amini
Street address
no 3, Yas building, In front of Asemane haftom travel agancy, Mir street, Nazar crossroads, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Islamic Azad University khorasgan branch
Full name of responsible person
Elmira Ahmadpour
Street address
Islamic Azad University, Khorasgan, Isfahan, Iran
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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
Isfahan Islamic Azad University khorasgan branch
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
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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