Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the postoperative pain after root canal therapy(in asymptomatic patients) with two different preparation methods (A randomized clinical study)

Protocol summary

Summary

The purpose of this study is to compare the postoperative pain prevalence in Wave one system and Protaper rotary files. Inclusion criteria: Patient age 15-55; One or multi rooted teeth with closed apex (molar and premolar); Teeth with asymptomatic irreversible pulpitis or asymptomatic necrosis; Intermediate root curvature Exclusion criteria: consumption of medicine before treatment(antibiotic and analgesics); Sinus tract; Retreatment. Forty two patients referred to the Endodontic Department of Tehran University of Medical Sciences from 20/12/2013 to 20/03/2014 which have single or multiple rooted teeth (Premolar and Molar teeth) are chosen according to inclusion and exclusion criteria . After explaning the process to the patients and getting an informed concent , the patient enters the study Patients are distributed into two groups of twenty one by Stratified Randomization and are treated in two appointment by one particular postgraduate student . Preoperative pain is recorded according to VAS (Visual Analog Scaling) . After injection of local anesthesia (Lidocaine 2%with 1/80000 Epinephrine) access cavity was prepared , then clamp and rubber dam were placed .Then the initial working length is determined with apex locator and periapical radiography Following that canal preparation is done with one of the 2 different methods evaluated in this study. In one group preparation is done by Wave one (single file).Then the canals were obturated and sealed with gutta-percha and AH26 sealer using standard spreader by lateral compaction technique. Our primary outcome is post operative pain

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071313970N1**

Registration date: **2014-03-07, 1392/12/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-07, 1392/12/16

Registrant information

Name

Azad Jamee

Name of organization / entity

dentistry faculty of tehran medical sciences university

Country

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-12-20, 1392/09/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the postoperative pain after root canal therapy(in asymptomatic patients) with two different

preparation methods (A randomized clinical study)

Public title
Comparison of the postoperative pain after root canal therapy(in asymptomatic patients) with two different preparation methods (A randomized clinical study)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:Patient age 15-55; One or multi roots teeth with closed apex (molar and premolar); Teeth with asymptomatic irreversible pulpitis or asymptomatic necrosis; Intermediate root curvature Exclusion criteria: Using any medicine before treatment(antibiotic and analgesics); Internal and external resorption which can be seen in radiography; Trismus; Sinus tract; Internal Ankylosis; Retreatment; Systemic disease or constant use of any medicine; Not filling the consent form; Trauma history; Pregnancy; Not being in occlusion ; Addiction to any drug; Lack of patient compliance in using the medicine accurately on time; Not obeying the usage protocol by patient or not trusting his/her; Not being able to use NSAID(because of side effects)before treatment or after using
Age
From **15 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee , Tehran University of Medical Sciences
Street address
No5, Qods Ave, Tehran
City
Tehran
Postal code
Approval date
2013-09-18, 1392/06/27
Ethics committee reference number
130/1421/92/ص

Health conditions studied

1

Description of health condition studied
Asymptomatic Necrosis of the pulp
ICD-10 code
k04.1
ICD-10 code description
Asymptomatic Necrosis of the pulp

2

Description of health condition studied
Asymptomatic irreversible pulpitis
ICD-10 code
k04.0
ICD-10 code description
Asymptomatic irreversible pulpitis

Primary outcomes

1

Description
Post operative pain
Timepoint
0-6-12-18-24-48-72
Method of measurement
VAS

Secondary outcomes

1

Description
Analgesics consumption
Timepoint
0-6-2-18-24-48-72
Method of measurement
Number of Analgesic consumption

Intervention groups

1

Description
Root canals prepared by Wave one technique
Category
Treatment - Other

2

Description
Root canals prepared by Rotary Protaper technique

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry, Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Hossein Nekoofar
Street address
North Karegar Ave,Tehran,iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Hossein Nekoofar
Street address
North Karegar Ave,Tehran, Iran
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Tehran
Grant name
Grant code / Reference number
92-03-69-22904
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
School of Dentistry, Tehran University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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