

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 explaining the process to the patients and getting an informed consent , 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

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Name of organization / entity
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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

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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**

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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