

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of root canal preparation using four single endodontic file techniques on postoperative pain, a randomized clinical trial

Protocol summary

Summary

The aim of this study is to compare the pain following single file root canal preparation by using Race , Neoniti and Mtwo files and two conventional method by using Race and Mtwo files. three In this double blind study, sixty three consented patients having the inclusion criteria will be randomly into three groups of 21 according to the type of tooth and their number of root canals. We will use minimization technique for randomization. After local anesthesia injection (Lidocaine with 1/80000 epinephrine, Daroupakhsh, Tehran, Iran), access cavities will be prepared and rubberdam isolation will be accomplished. Working length determination will be done by an electronic apex locator (Root ZX, J Morita, Tokyo, Japan) and confirmed by radiographic imaging. Root canal preparation will be accomplished by one of the following three instrumentation systems in a single file technique. a. Neoniti A1 25.08 (Neolix, France) b. RACE 25.06 (FKG Dentaire, La-Chaux-de-Fonds, Switzerland) c. Mtwo 25.06 (Sweden and Martina, Padua, Italy) 5.25% sodium hypochloride will be used for irrigation during instrumentation. Afterwards the smear layer removal will be accomplished by 17%EDTA (Calasept, Nordiska Dental, Angelholm, Sweden) and 2% chlorhexidine liquid (Calasept, Nordiska Dental, Angelholm, Sweden) will be used as the final irrigant. Subsequently obturation will be done with gutta-percha and AH26 sealer using a lateral compaction technique. At the end of the first appointment a single dose of 400 mg Ibuprofen (Gelofen®, Jabberebne Hayyan, Tehran, Iran) will be taken by the patient. Nine other capsules will also be provided to them. Postoperative pain levels will be recorded by a blind operator every 6h up to 7 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506167963N2**

Registration date: **2015-09-22, 1394/06/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-22, 1394/06/31

Registrant information

Name

Mohsen Aminsobhani

Name of organization / entity

Tehran University of Medical Sciences, Faculty Of Dentistry

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 0567

Email address

maminsobhani@irimc.org

Recruitment status

Recruitment complete

Funding source

Neolix company AJA University of Medical Sciences

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of root canal preparation using four single endodontic file techniques on postoperative pain, a randomized clinical trial

Public title

Effect of different root canal preparation techniques on the after treatment pain experienced by patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: consented patients between the ages of 15 to 55 years; having no systemic disease; needing primary root canal treatment; an asymptomatic premolar or molar tooth; having either asymptomatic irreversible pulpitis or pulp necrosis without any apical pathosis

Exclusion criteria: having symptoms prior to treatment initiation; root canal curvature more than 25 (measured by Schneider's method); having any systemic disease; requiring endodontic retreatment; having any periapical pathosis

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

Etemad zadeh avenue, Fatemi st.

City

Tehran

Postal code

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.AJAUMS.REC.1394.12

Health conditions studied

1

Description of health condition studied

asymptomatic irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

2

Description of health condition studied

asymptomatic necrosis of the pulp

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes

1

Description

pain

Timepoint

6 hour intervals after treatment up to 7 days

Method of measurement

numerical rating scale (NRS)

Secondary outcomes

1

Description

number of consumed analgesics

Timepoint

6 hour time intervals

Method of measurement

number of tablets

Intervention groups

1

Description

Mtwo 25.06

Category

Treatment - Devices

2

Description

Full sequence Mtwo

Category

Treatment - Devices

3

Description

Neoniti A1 25.08

Category

Treatment - Devices

4

Description

RACE 25.06

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, AJA University of Medical Sciences

Full name of responsible person

Mohsen Aminsobhani

Street address

Shahid Gohari St, Moalem St, Shariati St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AJA University of Medical Sciences

Full name of responsible person

Kamran Azma

Street address

Shahid Etemadzade St, West Fatemi St

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

AJA University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Neolix Company

Full name of responsible person

Xavier Rolland

Street address

11 Avenue Raoul Vadepied, 53600 Châtres-la-Forêt, France

City

CHÂTRES-LA-FORET

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Neolix Company

Proportion provided by this source

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

AJA University of Medical Sciences

Full name of responsible person

Mohsen Aminsobhani

Position

Endodontist

Other areas of specialty/work

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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