Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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, Switzerlan) 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

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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 irriversible 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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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